EPA Registration Jacket 66963-8



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511P)

1200 Pennsylvania Avenue NW Washington, DC 20460 EPA Reg. Number:

Date of Issuance:

66963-8

MAY 0 6 2008

Term of
Issuance:

Unconditional

Name of Pesticide Product:

Aloe Herbal Horse Spray

NOTICE OF PESTICIDE:

X Registration

___Re-registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Espree Animal Products, Inc.

P.O. Box 3650

Grapevine, TX 76051

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If the EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

The product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

- 1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
- 2. Have the label bear the identifying EPA Registration Number EPA Reg. No. 66963-8 before you release the product for shipment.
- 3. Submit two (2) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of the final printed label.

Signature of Approving Official:

Date:

5-6-08

W. Michael McDavit, Associate Director

W. Michael MSE

Biopesticides and Pollution Prevention Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

MEMORANDUM

DATE:

04/21/2008

SUBJECT:

Science Review in Support of the Registration of Aloe Herbal Horse Spray.

Response to Product Chemistry Deficiencies.

EPA File Symbol. Nos.: 66963-8

Decision No.:

390433 350305

DP Barcode: PC Codes:

011550, 021901, 040505

CAS Nos.

42822-86-6, 8000-29-1, 8000-27-9

MRIDs:

4731680I

Tolerance Exemption: Not Applicable

FROM:

Russell S. Jones, Ph.D., Senior Biologist /s/ 04/21/2008

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511P)

TO:

Chris Pfeifer, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to a request for additional information, the registrant has submitted additional physical and chemical properties data for the repellent product, Aloe Herbal Horse Spray, to fulfill conditions for registration.

RECOMMENDATIONS AND CONCLUSIONS

The submitted physical and chemical properties are acceptable to support the conditions of registration. No amendments to the current label are needed based on these data.

2-hydroxy-alpha, alpha-4-trimethyl-cyclohexanemethanol 2

Citronella Oil, & Cedarwood Oil PC Codes: 011550, 021901, 040505 DP Number: 347997

EPA File No.: 66963-8

STUDY SUMMARIES

The registrant submitted the following physical and chemical properties data (MRID 47316801) to support the conditions of registration for Aloe Herbal Horse Spray (EPA Reg. No. 66963-8): Physical State, oxidation/reduction, corrosion characteristics, pH, viscosity, and relative density. The data are listed in the table below:

Table 1. Additional Physical and Chemical Properties for Aloe Herbal Horse Spray

Physical/chemical Property	Results	Test Method
OPPTS 830.6303 Physical State	Clear, colorless liquid at 25 C	Visual Inspection
OPPTS 830.6314 Oxidation/Reduction	No signs of reaction upon mixing or after 24 hours exposure	Test substance placed in contact with powdered iron or potassium permanganate and monitoring for any temperature rise and visual inspection for signs of corrosion as per 44 FR 16267 (March 16, 1979)
OPPTS 830.6320 Corresion Characteristics	HDPE container was concave on one side. No other changes noted.	Visual Inspection after 12 months storage at room temp, in commercial packaging (HDPE)
pH	4.90	ASTM Method No. E 70
Viscosity	18.266 m ² /s (cSt)	ASTM Method Nos. D445 & D446
Relative Density	0.8435 at 23 C	ASTM Method No. D 891, B
	1	

CLASSIFICATION: Acceptable.

NO DERS WERE WRITTEN FOR THIS REVIEW

cc: R. S. Jones, C. Pfeifer, BPPD Subject File/IHAD

R. S. Jones, Ph.D, Sr. Biologist, FT, OPY: 04/21/2008

DATA PACKAGE BEAN SHEET

Date: 13-Mar-2008
Page 1 of 3

Decision #: 390433

DP #: (350305) NON PRIA

Parent DP #:

Submission #: 822389

* * * Registration Information * * *

Registration:	66963-8 - ALOE HERE	BAL HORSE SPRA	Υ		
Company:	66963 - ESPREE ANIMAL PRODUCTS, INC				
Risk Manager:	RM 91 - Driss Benmhend - (703) 308-9525 Room# F	'Yt S-8955		
Risk Manager Reviewer:	Jay Pfeifer JPFEIFER				
Sent Date:	09-Jan-2008	Calculated Due Dat	e: <u>27-Apr-2008</u>	Edited Due Date:	
Type of Registration:	Product Registration - Section	on 3			
Action Desc:	(575) CONDITIONAL REGIS	STRATION FOLLOW-UP	;DATA REQUIRI	ED;REQUIRES SCIENCE	
Ingredients:	See page 3				·
	* * * D	ata Package In	formation *	* *	
Expedite:	◯ Yes ● No	Date Ser	t: t3-Mar-2008	Due Back:	
DP Ingredient:	See page 3				
DP Title:	Phys Chem Characteristics				
CSF Included:	○ Yes ● No Lab	el Included: O Yes	No Pare	nt DP #:	
	•				
Assigned To	0	Date In	Date Out		
Organization: BPPD	/ BPB			Last Possible Science Due Date:	t7-Feb-2008
Team Name: RM 9 t				Science Due Date:	
Reviewer Name: Jones	, Russell			Sub Data Package Due Date:	
Contractor Name:				•	
***************************************				•	
	* * * Stu	dies Sent for R	eview * * *		

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review to see if it satisfies condition of registration. Please comment on whether labeling might need to be changed as a result of any new conclusions.

DP#: (350305)	* * * Studies Sent for Review * * *	Decision#: (390433)
MRID MRID Status	Citation Reference	Guideline
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.6303/Physical state
4731680 t	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.6314/Oxidizing or reducing action
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	_
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7000/pH of water solutions or suspensions
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7100/Viscosity
4731680 t	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7300/Density/relative density

Page 3

PC Code	CAS	Ingredient Name
011550	42822-86-6	Cyclohexanemethanol, 2-hydroxy- alpha., alpha., 4-irimethyl-
021901	8000-29-1	Oil of citronella
040505	8000-27-9	[Cedarwood oil
0t1550	42822-86-6	Cyclohexanemelhanol, 2-hydroxyalpha.,.alpha.,4-trimelhyl-(.378%)
040505	8000-27-9	Cedarwood oil(.5%)
02190 t	8000-29-1	Oil of citronella(.75%)

*** Studies Sent for Review ***

Dr#: (350975)	Studies Sent for neview " "	Decision#: (388684)
MRID MRID Status	Citation Reference	Guideline
47324601	Kiely, K.; Killinger, T.; Maher, M. (2008) Product Identity,	880.1100/Product identity and
77024001	Composition, and Production: Bedoukian e.e-9,	composition
	11-Tetradecadienyl Acetate Technical Pheromone. Unpublished	oompositori
	study prepared by Keller and Heckman LLP. 174 p.	
4732460 t	Kiely, K.; Killinger, T.; Maher, M. (2008) Product Identity,	880.1200/Description of starting
	Composition, and Production: Bedoukian e.e-9,	materials, production and
	11-Tetradecadienyl Acetate Technical Pheromone. Unpublished	formulation process
	study prepared by Keller and Heckman LLP. 174 p.	•
47324601	Kiely, K.; Killinger, T.; Maher, M. (2008) Product Identity,	880.1400/Discussion of termation of
	Composition, and Production: Bedoukian e,e-9,	impurities
	11-Tetradecadienyl Acetate Technical Pheromone, Unpublished	,
	study prepared by Keller and Heckman LLP. 174 p.	
47324602	Maher, M. (2008) Preliminary Analysis and Certified Limits:	830.1700/Preliminary analysis
	Bedoukian e,e-9, t1-Tetradecadienyl Acetate Technical	• •
	Pheromone. Unpublished study prepared by Bedoukian	
	Research, Inc. 23 p.	
47324602	Maher, M. (2008) Preliminary Analysis and Certified Limits:	830.1750/Certitied limits
	Bedoukian e,e-9,11-Tetradecadienyl Acetate Technical	
·	Pheromone. Unpublished study prepared by Bedoukian	
	Research, Inc. 23 p.	
47324603	Kiely, K. (2008) Enforcement Analytical Method: Bedoukian	830.1800/Enforcement analytical
	e,e-9,11-Tetradecadienyl Acetate Technical Pheromone.	method
	Unpublished study prepared by Bedoukian Research, Inc. 32 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.6302/Color
	Bedoukian e,e-9,11-Tetradecadienyl Acetale Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.6303/Physical state
	Bedoukian e,e-9, t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.6304/Odor
	Bedoukian e,e-9,11-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.63 t3/Stability to sunlight,
	Bedoukian e,e-9,11-Tetradecadienyl Acetate Pheromone.	normal and elevated temperatures,
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	metals, and metal ions
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.6315/Flammability
	Bedoukian e,e-9, t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.63 t7/Storage stability of product
	Bedoukian e.e-9, t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.6320/Corrosion characteristics
	Bedoukian e.e-9, t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7050/UV/Visible absorption
	Bedoukian e,e-9,11-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7100/Viscosity
	Bedoukian e,e-9, t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7200/Melting point/melting
	Bedoukian e,e-9,11-Tetradecadienyl Acetate Pheromone.	range
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7220/Boiling point/boiling range
	Bedoukian e.e-9,t1-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7300/Density/relative density
	Bedoukian e,e-9,1 t-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7550/Partition coefficient
	Bedoukian e,e-9,1 t-Tetradecadienyl Acetate Pheromone.	(n-octanol/water), shake flask
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	method
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7840/Water solubility: Column
	Bedoukian e.e-9,11-Tetradecadienyl Acetate Pheromone.	elution method, shake flask method
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	
47324604	Kiely, K.; Maher, M. (2008) Physical Chemical Properties:	830.7950/Vapor pressure
	Bedoukian e.e-9,11-Tetradecadienyl Acetate Pheromone.	
	Unpublished study prepared by Bedoukian Research, Inc. 106 p.	

Decision#: (388684)

Page 3					
DP#: (3509	75)	* * * Additiona.	uta Package for this D	ecision * * *	Jecision#: (388684)
DP#	Divisio	on/Branch [Date Sent Date Due	Instructions?	CSF label
349478	BPPD / BPB	t4	4-Feb-2008 07-Feb-2008	3 ⊘ Yes ⊝ No €	Yes 💮 No 🌘 Yes 🕥 No
349478	BPPD / BPB	14	4-Feb-2008 07-Feb-200	8 ⊚ Yes ⊚ No - (Yes 💮 No 🌘 Yes 💮 No

Receipt for Section 3		
S: 822389 Resubmission C	Annual Control of the	Print Letter
Regulatory Type: Product Registration - Section 3 Fee For Service	Yes (* No.)	Enter More Information
Application Type: Miscellaneous Receipt Company: 56983 ESPREE ANIMAL PRODUCTS, INC V	101) 100	Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91 Product # 66963-8 Product Name: ALOE HERBAL HORSE SPRAY		And the second s
Override# Me Too Me Too Product Name:		
Application Date: 07-Jan-2008 CPP Rec've Date: 08-Jan-2008		Receipt Content
Front End Date: 09-Jan-2008 ic Risk Manager Send Date: 09-Jan-2008 FFS Due Date: Negotiated Due Date: 09-Jan-2008 OPP Target Date: 7	Study	
Fast Track: The New Ingredient: The Receipt Description:		
physical/chemical properties FEB 2 9 2008	New Ingredient Request Date:	
	New Ingredient Received Date	
61V/M48M41F1V19AM4M31SV8AX	7.0	

Please Janvand to Chris
Please Janvand to Chris
Please Janvand to Chris

MAR 0 3 2008

P.S. This shudy is submitted for the purpose of lefting the condition on the refishmation of 60963-8.

AIO-Chris P. MAR 4 2008



122 C Street, N.W., Suite 740 Washington, D.C. 20001 telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs

January 7, 2008

HAND DELIVERED

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington VA 22202

ATTENTION:

Velma Noble

Product Manager, Team 🔊

SUBJECT:

Espree Animal Products, Inc.

Aloe Herbal Horse Spray (EPA Reg. No. 66963-8) Submission of Physical/Chemical Properties Study

Dear Ms Noble:

On behalf of Espree Animal Products, Inc., we are submitting three (3) copies of the following Physical/Chemical Properties study as required by the registration conditions for Aloe Herbal Horse Spray (EPA Reg. No. 66963-8):

VOLUME 1 of 1:

Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH. Viscosity and Relative Density (November 20, 2007) by David J. Sinning, Case Consulting Laboratories, Inc.; Study No.: 3660-01; 7 pages.

OPPTS: 830.6303, 830.6314, 830.6320, 830.7000, 830.7100,

830.7300

MRID Number:

47316801

If you have any questions and/or comments about the enclosed submission, please feel free contact me by phone at 202-393-3903 (ext. 19) or by email georgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

Agent for,

Espree Animal Products, Inc.

Memorandum

Date:	1/10/08	
To:	<u> (24 91 91 </u>	, Regulatory Manager
From:	Information Service	s Branch, ITRMD
indication	ur receipt of this data on that MRIDs for the sted to OPPIN.	submission is not an e enclosed studies have
from th	· · · · · · · · · · · · · · · · · · ·	e approximately 5 days the study-level data is
•	ou have any question contact Teresa Downs	
This is a	a: fully accepte partially accepte rejected subn	epted submission
		and 57

11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

January 10, 2008

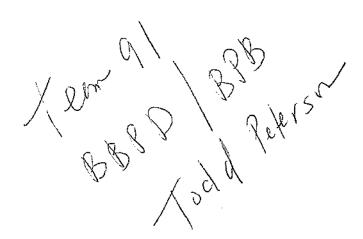
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

ESPREE ANIMAL PRODUCTS, INC 122 C STREET, NORTHWEST, SUITE 740 WASHINGTON, DC 20001-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-JAN-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Leonard Cole

7023933906

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved. OMB No. 2070-0044. Approved Expires 1-S1-96

United States

Environmental Protection Agency

Office of Pesticide Programs (7505C) Woshington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor,

EPA Ragistration Number of Product	Distributor Company Number
66963-8	84767
Note: Do not submi	t distributor product labels
Name of Registered Product Uselo product name accepted by EPA) Also Herbal Horse Spray	Distributor Product Name Larry's Horse Spray
Name and Advised of Designate (Tube include 7th anda)	

Lorry's Tack 25598 E. Baseline San Bemardino, CA. 92410

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- The product must ramain in the manufacturer's unbroken container.
- The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

	<u>- </u>	·
	Distributor	
We intend to market our product under the Digitib.	utor Product Name specified above, subject to the co	nditions specified on this Notice.
Signature and Jule of Specific	Lever E Mitchestor	Date _{n on a} constitution of the constitution
172 11	- UWDa	12-05-07
		3 3 3

Registrant

) agree that the distributor nemed above mey distribute and sell the Distributor Product specified above, aubject to the conditions specified on this Matica.

araC) Signature and Hale of Registrant

EPA Forth 8570-5 (Roy, 254) Previous aditions are obsolete.

White - EPA

MATERIAL TO BE ADDED TO JACKET

REG#			6696	1-1	66963-8
Description:		ion:	New Reg	estrati	M
ł	cho	ok all tha	topply		
	CHEC	ck all that			
	Ø	new st	amped accept	ed labe	Send
		new C	SF		6
		notifica	ation		CSC
new ma finding r paper th CSF fol-	his shee terial in material nen hold <u>der</u> (if re	et to the top of jackets). This in the e-jacket together with	f ALL material sent to the s sheet will be imaged; a c et. <u>Remove staples</u> from a n a binder or paper clip. C t) or covered with a <u>red Cl</u> ed to file room should be p	clear description all material. If SFs should be BI sheet (if ret	on will aid in returning loose e placed in the turning loose
Reviewe Nar	er's me:	Toda	Peterin	Date:	UN % 7 2007
Pho		308-1	7224	Division:	BPPD

UNITED .. ATES ENVIRONMENTAL PROTECTION



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 1200 Pennsylvania Avenue NW Washington, DC 20460

EPA	Reg
Nun	iber.

Date of Issuance:

66963-8

JUN 1 3 2007

Term of

Conditional

Name of Pesticide Product:

Aloe Herbal Horse Spray

NOTICE OF PESTICIDE:

Registration

Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Espree Animal Products, Inc.

P.O. Box 3650

Grapevine, TX 76051

Note: Chaoges in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others,

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(A) provided you:

- 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Submit within 9 months data package for Guideline Study: OPPTS 830.6320 (Corrosion Characteristics).
- 3. Revise the EPA Registration Number to read, "EPA Reg. No. 66963-8".
- 4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

This registration is effective for 1 year from the date of issuance.

	Signature of Approving Official:		Date:	
	(See secon	d page for signature)	6/13/	67
MBOL	7511P	CONCURRENCES		
RNAME)	SPA Form 8570-6 してピッシュ	***************************************	******* *******************	*************
TE (/12/07	*******************************	*************************	
PA Form 132	0-1A (1/90)	Printed on Recycled Paper		OFFICIAL FILE COPY

Page 2

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely, W. Michael Mc Dont

Janet L. Andersen, Ph.D., Director Biopesticides and Pollution

Prevention Division (7511P)

ACCEPTED

JUN 1 3 2007

Under the Pederal Introduction In Fungleide, and Redemicide In tered wader.

ALOE HERBAL HORSE SPRAY

Fly Repellent

Concentrate Repels Flies and Gnats Contains Aloe Vera, Sunscreen and Coat Conditioners

Active Ingredients:

Citronella Oil 0.750% 0.500% Cedarwood Oil Eucalyptus Oil 0.378% Other Ingredients: 98.372% TOTAL: 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

	FIRST AID						
Have the p	Have the product container or label with you when calling a poison control center or doctor, or						
going f	for treatment. You may also contact 1-800-328-1317 for additional information.						
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. 						
}	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.						
	Call a poison control center or doctor for further treatment advice.						
If on skin:	Take off contaminated clothing.						
	• Rinse skin immediately with plenty of water for 15-20 minutes.						
	Call a poison control center or doctor for treatment advice.						

EPA Reg. No. 66963-I

Net Contents: 32 fl oz. (946 ml)

Manufactured By: Espree Animal Products, Inc. 3250 Stone Myers Parkway Grapevine, TX 76051 www.espree.com 1-800-328-1317

Page 1 of 2

EPA Est. No.: 66963-TX-001

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

A gentle blend of ingredients, including botanical oils, to repel flies, gnats and other flying insects on horses. Aloe Herbal Horse Spray contains coat conditioners and sunscreen which promote a healthy coat and protection from the sun.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. SHAKE CONTIANER BEFORE EACH APPLICATION.

General Directions: Apply in a covered area (i.e., stalls, barn, etc.). Brush coat to remove excess dirt and dust. For best results apply to a clean horse.

<u>Dilution Directions</u>: To be used in a clean spray container of your choice. Dilute with 5 parts water to 1 part horse spray. When pest pressure is high, dilute 4 parts water to 1 part horse spray.

<u>Application Directions:</u> Hold spray container 10 to 12 inches from coat for best application. Apply with cloth to facial area.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store only in a cool, dry area inaccessible to children and pets. Keep container tightly closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be used on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 800-CLEANUP for disposal instructions.

Never place unused product down any indoor or outdoor drain.

EPA Reg. No.: 66913-I RAL: Peterson Application Date: 14/01

#	Check list item (***) *** *** *** *** *** **** **** *							
1.	Application Form (EPA Form 8570-1) - signed & complete including package type? IF NO, STOP ! Call applicant and have them correct application and resubmit.	V						
2.	If amendment, was final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling.							
3.	Confidential Statement of Formula (CSF) EPA Form 8570-4 Basic Formula Alternate Formula	ı(s) 💢 _	1					
a,	CSF Review completed? IF YES, SKIP to ITEM 4. Nina did review	X						
b.	CSF is signed and dated? IF NO, CALL APPLICANT.							
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?							
d.	Are the totals accurate?		<u></u>					
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).							
f.	Viability (if live microbial, i.e., cfu/gram)? NA □							
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?							
h.	List 1 inert ingredient(s) present in the formulation? If YES, be sure it is listed on the label.							
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs per 40 CFR 152.43(b)(3).							
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)	7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7						
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES , RAL must evaluate label directions for compliance with 40 CFR 180.1071.							
4.	Data and Data Matrix present. (EPA Form 8570-35)	×						
a.	a) Using Selective Method? [IF NO, SKIP to ITEM 5 since data matrix required for selective method.]	×	-					
b.	Complete Data Matrix supporting both the product registration and, if applicable, the proposed amendment. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.	X						
c.	Adequate product specific data submitted? Covrosion chan due	X						
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 5. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) If NO or if use not supported by registered source, generic data is necessary.		×					
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?	X						
f.	Public copy of Data Matrix provided? (PRN 98-5)		X					
5.	Certification with Respect to Citation of Data (EPA Form 8570-34): See 40 CFR 152.80-98 and P [Note: If no data are required or submitted, form is not needed. This is often true for minor amendments.]	R Notice	98-5					
a.	Did applicant check a Method of Support?	<u> </u>						
Ъ.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	メ						
c.	Is the form signed and dated?	メ						
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?	强	X					
e.	IF YES, is the required authorization letter included in application?							
6.	Formulators Exemption (EPA Form 5870-27)							
a.	If registrant is using a registered source active ingredient in the formulation (manufacturing-use product), is form filled out completely and signed?	19						

#	Check list frem				
7.	Exclusive Use Notice Requirement Prior to Registration (Required per 40 CFR 152.116,				
	separate from permission of an exclusive use data submitter to rely on exclusive use data)		×		
	Is this an exclusive use active ingredient or mix of active ingredients (registered w/in last 10 yrs)? If YES, go to a) or b) below.				
a.	a) Has a notification of intent to register letter or email been sent to the exclusive use data submitter(s) at least 30 days before registration? (This notification is required for all methods of data support except when the exclusive use data submitter(s)' product is used to formulate and the formulator's exemption is claimed.)		· · · · · · · · · · · · · · · · · · ·		
b.	Has exclusive use data submitter requested during 30 day period the applicants list of data requirements and method of compliance?				
c.	Has registrant submitted certification from exclusive use data submitter that submitter is aware of the application and does not object to the registration?				
8.	Science Review completed? Comments:	*			
9.	Y abal(a) Pardami				
ļ	Label(s) Review <u>Date of Label Review:</u> Label(s) in conference with a professional device of Label Review.	火			
a. b.	Label(s) in conformance with current Label Review Manual and appropriate REDS. Labeling statements and slaims are supported by Asute Toxicity. Product Chemistry data (or executable)				
0.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.	X			
C.	Nominal concentration of active ingredient shown in ingredients statement.	X			
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).				
e.	Storage and disposal instructions agree with container types listed on application form.	X			
f.	Unique Product Name for Same Company (Check OPPIN).	X			
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		X		
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		X		
	If YES, National Organic Program or OMRI claims approved by Bob Torla?				
i.	Labeling is acceptable. Corrections or changes are NOT necessary.	X			
j -	Comments:				
	BPPD Guidance Document - Other Items May be Required	August 2			

File Symbol: 66 967 Date: 6/4/07 Reviewer: There

[Site/Use]	(Res	/Ag=) /Bo	tn	1 [Food Non	-Food /Both I
[Tox Categories:]	[AcOral 4	AcDerm: 1 Actr	ihi(47	Eyel(r: TJskinlrrTD)	ermSens:
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide			*		Ch 6
Product Name	N/				Pg 12-3
Compny Name and Info	V				Pg 15- 1
Identification Numbers	V				Ch 14
Net Contents	>			More	Ch 17
Ingredients Statement	7			align Hr	Ch 5
Label Claims	->			Adjust	Pgs 4-5, 5-7 11-10 & Ch 12
Alternate Formula				NM 4	5-12

Alternate Formula				TViv.	5-12		
Precautionary Statements							
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3		
KOROC	l _a				3-1 & 9 7-3 & 4		
Signal Word	1,000				Ch 3 Ch 7 Ch 10		
General Heading >PRECAUTIONARY STATEMENTS=	and the second				Ch 7		
First Aid (PRN 20001-1)				Marian	Ch 3 & 7		
Hazards to Humans and Domestic Animals	V			, , , , , , , , , , , , , , , , , , ,	Ch 3, 7-3		
PPE (WPS) Engineering Controls			X		Ch 7, Pg 7-12 Pgs 10-4, 15		
User Safety Requirements			1		Ch 10		
User Safety Recommendations			X		Ch 10		
Environmental Hazards	V				Ch 8		
Physical and Chemical Hazards			入		Pg 3-4 Ch 9		

, Di	rections / US	E (FIFRA Text,	WPS pl	us Storage and L.spc	sal
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Header >Directions for Use=	l _{aboration} .				10-16
Violation of Federal Law text	Laderarch				10-26, 11-7
WPS Text (PPE)			×		Ch 10, 7-1 7-11
Non-WPS Text			×	John Market Mark	7-12, Ch 10
Storage and Disposal				(0) em/	11-16, Ch 13

Directions for Use (General instructions and information)						
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3	
General Instructions and Sub-Header				Move		
Chemigation / Prohibition			7		PRN	
REI			7		Pg 10-20	

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Info. (non-site specific into. on uses, pests, mixing, and loading, tank mixing, etc.)	V			Ge & Diell Many	
General Precautions and Restrictions					
		Directions	for Use		
Directions for Application					
*		Warranty Inf	formation	ı	
Consistency with label instructions				None	12-6
Not false or misleading					

"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, ato the extent allowable by state laws or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or injury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."

ALOE HERBAL HORSE SPRAY

Fly Repellent

1:5 Concentrate Repels Flies, Gnats and Mosquitoes Contains Aloe Vera, Sunscreen and Coat Conditioners 32 Fl oz. (946 ml)

Active Ingredients:	
Citronella Oil	0.75%
Cedarwood Oil	0.50%
Eucalyptus Oil	0.378%
Other Ingredients:	98.372%
TOTAL:	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

EPA-Règ. No. 66963-I

EPA Est. No.: 66963-TX-001

ALOE HERBAL HORSE SPRAY

A gentle, effective blend of natural botanical oils to repel flies, gnats, mosquitoes and other flying insects on horses. Contains coat conditioners and sunscreen which promote a healthy coat and protection from the sun. Made with human grade ingredients, Aloe Herbal Horse Spray provides your horse long lasting protection.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. SHAKE CONTIANER BEFORE EACH APPLICATION.

General Directions: Apply in a covered area (i.e., stalls, barn, etc.). Brush coat to remove excess dirt and dust. For best results apply to a clean horse.

<u>Dilution Directions</u>: To be used in a clean spray container of your choice. Dilute with 5 parts water to 1 part horse spray. For more stubborn cases, dilute 4 parts water to 1 part horse spray.

<u>Application Directions:</u> Hold spray container 10 to 12 inches from coat for best application. Apply with cloth to facial area. Do not use on animals intended for human consumption.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store only in a cool, dry area inaccessible to children and pets. Keep container tightly closed when not in use.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be used on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Have the p	FIRST AID Have the product container or label with you when calling a poison control center or doctor, or going for treatment.					
If on skin:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. 					
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for further treatment advice. 					

Manufactured By: Espree Animal Products, Inc. 3250 Stone Myers Parkway Grapevine, TX 76051

www.espree.com 1-800-328-1317

DATA PACKAGE BEAN SHEET

Date: 30-Apr-2007 Page t of 3 Decision #: 373758

DP #: (338682)

PRIA

Parent DP#:

		* * * Registration In	formation * * *	1700 - 1
Registration:	66963-I - ALOE	HERBAL HORSE SPRA	Υ	
Company:	66963 - ESPREE AN	IMAL PRODUCTS, INC		Due 1
Risk Manager:	RM 91 - Driss Benm	hend - (703) 308-9525 Room#	PY1 S-8955	/30/
Risk Manager Reviewer:	Todd Peterson TPE	TERSO		• /
Sent Date:	·	Calculated Due Da	te: 14-Jun-2007	Edited Due Date:
Type of Registration:	Product Registration	- Section 3		
Action Desc:	(B67) NEW PRODU	CT;NON-FAST TRACK;MICRO	BIAL/BIOCHEMICAL;	
Ingredients:	See page 3			
	*	* * Data Package Ir	nformation * * *	
Expedite:	◯ Yes ● No	Date Se	ent: 04-Apr-2007	Due Back:
DP Ingredient:	See page 3			
DP Title:	Product Chem and T	ox 6 Pack		
CSF Included:	● Yes ○ No	Label Included: Yes	○ No Parent DP #:	
			-	
Assigned T	<u>o</u>	Date tn	Date Out	
Organization: BPPD	/ BPB		Last Pos	sible Science Due Date: 14-Feb-2007
Team Name:				Science Due Date:
				Data Package Due Date:
	* *	* Studies Sent for F	(eview * * *	

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product chemistry and Tox six pack for old active ingredients in new end use product. Please review data packages attached, CSF and related label language in relation to submitted data.

Todd Peterson 703-308-7224

47029305-10 47029301 * * * Studies Sent for Review * *

MRID MRID Status Citation Reference Guideline 47029301 Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 830.1550/Product Identity and Identity and Composition Source Active ingredients. Unpublished composition study prepared by Espree Animal Products, Inc. 31 p. 47029302 Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 830.1550/Product identity and Identity and Composition, Beginning Materials, Formulating composition Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p. Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 830, t600/Description of materials 47029302 Identity and Composition, Beginning Materials, Formulating used to produce the product Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p. 47029302 Lewis & Harrison, LLC (2007) Aloe Herbai Horse Spray: Product 830. t650/Description of formulation Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, inc. 50 p. Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 830. t670/Discussion of formation of 47029302 Identity and Composition, Beginning Materials, Formulating impurities Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p. Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 47029302 830.1700/Preliminary analysis Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p. Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product 830, t750/Certified limits 47029302 Identity and Composition, Beginning Materials. Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p. 47029303 Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Wavier 830.1800/Enforcement analytical Request for Enforcement Analytical Method and Storage Stability. method Unpublished study prepared by Espree Animal Products, Inc. 9 p. 830.63 t7/Storage stability of product 47029303 Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Wavier Request for Enforcement Analytical Method and Storage Stability. Unpublished study prepared by Espree Animal Products, Inc. 9 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.6303/Physical state 47029304 Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.6314/Oxidizing or reducing 47029304 Herbal Horse Spray: Physical State, Oxidation/Reduction, action Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.6320/Corrosion characteristics 47029304 Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.7000/pH of water solutions or 47029304 suspensions Herbal Horse Spray, Physical State, Oxidation/Reduction, Corrosion Characterístics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.7100/Viscosity 47029304 Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p. Sinning, D. (2006) Physical and Chemical Characteristics of Aloe 830.7300/Density/relative density 47029304 Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, inc. 7 p. Durando, J. (2006) Aloe Herbai Horse Spray: Acute Oral Toxicity 870.1 t00/Acute Oral Toxicity 47029305 Up and Down Procedure in Rats, Project Number: 2110t, P320/UDP. Unpublished study prepared by Product Safety Laboratories, 14 p.

Decision#; (373758)

Page 2

DP#: (338682)

* * * Studies Sent for Review * *

Decision#: (373758) MRID MRID Status Citation Reference Guideline Durando, J. (2006) Aloe Herbal Horse Spray: Acute Dermal Toxicity Study in Rats - Limit Test. Project Number: 21102, 870. t200/Acute dermal toxicity 47029306 P322/RAT. Unpublished study prepared by Product Safety Laboratories. 14 p. Durando, J. (2006) Aloe Herbal Horse Spray: Acute Inhalation Toxicity Study in Rats - Limit Test. Project Number. 21 to3, P330. 47029307 870.1300/Acute inhalation toxicity Unpublished study prepared by Product Safety Laboratories. 22 Durando, J. (2006) Aloe Herbal Horse Spray: Primary Eye Irritation Study in Rabbits. Project Number: 21104, P324. Unpublished study prepared by Product Safety Laboratories. 17 47029308 870.2400/Acute eye irritation Durando, J. (2006) Aloe Herbal Horse Spray: Primary Skin 870.2500/Acute dermal irritation 47029309 Irritation Study in Rabbits. Project Number: 21105, P326. Unpublished study prepared by Product Satety Laboratories. 15 Durando, J. (2006) Aloe Herbal Horse Spray: Dermal Sensitization 870.2600/Skin sensitization Study in Guinea Pigs (Buehler Method). Project Number: 21106, P328. Unpublished study prepared by Product Safety 470293 to Laboratories, 23 p.

Page 3

DP#: (338682)

** Product and Data Package Ingredients * * *

Decision#: (373758)

PC Code	CAS	Ingradient Name
01 t550	42822-86-6	Cyclohexanemethanol, 2-hydroxyalpha.,.alpha.,4-trimethyl-
021901	8000-29-t	Oil of citronella
040505	8000-27-9	[Cedarwood oil
01 t550	42822-86-6	Cyclohexanemethanol, 2-hydroxy-,alpha.,alpha.,4-trimethyl-(.378%)
040505	8000-27-9	Cedarwood oil(.5%)
021901	8000-29-1	Oil of citronella (.75%)

Page is not included in this copy.
Pages 30_ through 33 are not included in this copy.
The material not included contains the following type of information:
X Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

RIDGE NATIONAL LABORATORY

MANAGED BY UT-BATTELLE FOR THE DEPARTMENT OF ENERGY

April 27, 2007

CUSTODY RECEIPT FOR FIFRA CONFIDENTIAL BUSINESS INFORMATION

TO: Pamela Landis

Biopesticides and Pollution Prevention Division

Office of Pesticide Programs

U.S. Environmental Protection Agency.

One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202

FROM:

R. H. Ross, Group Leader

Toxicology and Hazard Assessment Group

1060 Commerce Park

Oak Ridge, Tennessee 37830

(865) 574-7797 FAX (865) 574-5353

email rossrh@ornl.gov

INSTRUCTIONS:

Original of this receipt to be signed by recipient and returned to sender.
 Duplicate of this receipt to be retained by recipient.

						Н	ours
TASK No.	MRID No.	Chemical/Agent	WAM	Material Sent	Status	Est.	Actual
07-33	47029301-10*	Aloe Herbal Horse Spray	1	7 DERs 10 Study reports I Custody sheet 1 CD	Draft	60	50

^{*}Note that MRID 47029304 was not on the task sheet

I have personally received from the sender material, enclosure	es, and attachments as identified above. I assume full
responsibility for the safe handling, storage, and transmittal o	f this material in accordance with existing FIFRA Confidential
Business Information regulation	O_{i} O_{i}
DATE RECEIVED: 4/30/07	SIGNATURE: Chal of Re-

WAM Tickler (Version 091206)

Dark line boxes without yellow are info entered later in process, for now enter info for items in yellow fields / click on left most cell in box to start

Data Type (see Key	for types)	MRIDs list by type of data	
P	470293	-01, -02, -03,	
Τ	470293	-05, 06, 07, 08, 09, 10	

PRIA Code	67	KEY:	Р	product chemistry
enter	B70 is 70		ÌΕ	efficacy
number only	B58 is 58		. N	non-target organism/eco effects
	·		Т	toxicology (human health)
OPPIN Start	2/14/2007		О	other
Date	mm/dd/yy			
Based on FFS	/ fee accepted		(oth	er includes insect resistance management
or waiver acc	epted date		supp	lemental data, BRAD development, etc.)

Date RAL sent pkg to WAM ---->

04/04/07 mm/dd/yy

Work Assignment #	
Return Date>	
(entered by WAM)	
Phase IV Sent Date:	
(RAL to enter this date wh	en moving package to Phase IV)
Phase IV Due Date>	5/30/2007 ulated)

	days	end date
Phase 1	45	3/31/2007
Phase 2	0	3/31/2007
Phase 3	30	4/30/2007
Phase 4	30	5/30/2007
Phase 5	0	6/14/2007
Docs	7.5	6/6/2007
OGC	0	6/6/2007
Decision	7.5	6/14/2007

War X
(3) 30/13 min
Soul of the state of the
DERS Showmen but
Use this box for hand written notes

when time frames shift or PRIA date is negotiated, etc. OR note if not PRIA PRINT this form in B&W

color is not necessary

Comments:

DATA EVALUATION RECORD

CITRONELLA OIL CEDARWOOD OIL EUCALYPTUS OIL (Aloe Herbal Horse Spray)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1100)

Description of Beginning Materials (OPPTS 830.1200)

Description of Formulation Process (OPPTS 830.1200)

Discussion of Formation of Impurities (OPPTS 830.1400)

Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750)

Enforcement Analytical Method (OPPTS 830.1800)

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 47029301-47029304

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 07-033

Primary Reviewer: Eric B. Lewis, M.S.

Secondary Reviewers:

Sylvia Milanez, Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Lee Ann Wilson, M.A. Signature:

Date:

Signature: Date:

Signature: Date:

Signature

Date:

Disclaimer

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE: Product Identity and Composition (OPPTS 830.1100)

Description of Beginning Materials (OPPTS 830.1200) Description of Formulation Process (OPPTS 830.1200) Discussion of Formation of Impurities (OPPTS 830.1400)

Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750)

Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-

830.7950)

MRID NO: 47029301-47029304

DECISION NO: 373758

DP BARCODE: DP338682

TEST MATERIAL: Aloe Herbal Horse Spray (a.i., 0.75% w/w citronella oil;

0.50% w/w cedarwood oil; 0.378% w/w eucalyptus oil)

PROJECT STUDY NO: MRID 47029301 - 47029303: Not provided

MRID 47029304: Study No. 3660-01

SPONSOR: Espree Animal Products, Inc., 3250 Stone Myers Parkway,

Grapevine, TX 76051

TESTING FACILITY: MRIDs 47029301 - 47029303: None

MRID 47029304: Case Consulting Laboratories, Inc., 622

Route Ten, Whippany, NJ 07981

TITLE OF REPORT: MRID 47029301: Aloe Herbal Horse Spray: Product Identity

and Composition. Source Active Ingredients

MRID 47029302: Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified

Limits.

MRID 47029303: Aloe Herbal Horse Spray: Waiver Request for Enforcement Analytical Method and Storage Stability MRID 47029304: Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density

AUTHORS: MRIDs 47029301 - 47029303: Lewis & Harrison, LLC

MRID 47029304: Sinning, D.J.

STUDY COMPLETED: MRIDs 47029301 - 47029303: January 3, 2007

MRID 47029304: November 28, 2006

GOOD LABORATORY MRID 47029301: A signed and dated GLP statement was

PRACTICE: included. The report is a discussion of product identity of the source active ingredients. The information was provided to the

registrant, and the registrant does not know if GLP standards

were used.

MRID 47029302: A signed and dated GLP statement was included. The report is a discussion and GLP standards do not

Inert ingredient information may be entitled to confidential treatment

apply.

MRID 47029303: A signed and dated GLP statement was included. The report is a waiver request, and GLP standards do not apply.

MRID 47029304: A signed and dated GLP statement was included. The study was conducted in compliance with GLP standards. The test substance stability, synthesis, and characterization are held by the sponsor, and the performing laboratory does not know if these data conform to GLP standards.

CONCLUSION:

Aloe Herbal Horse Spray is an end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. CSFs for a basic and an alternate formulation were provided. The active ingredients in both formulations (w/w) are 0.75% citronella oil, 0.50% cedarwood oil, and 0.378% eucalyptus oil. The inert ingredients (w/w) in the basic

formulation are

ingredients. Adequate descriptions of the beginning materials were provided. The product is formulated by a simple blending of the active and inert ingredients, and no impurities are formed. Results of a preliminary analysis were not provided. In both formulations, the upper certified limit given for than the nominal concentration of the in the product. In the alternate formulation, the certified limits given for are incorrect. A waiver was requested for the requirement of an enforcement analytical method. The physical and chemical characteristics were adequately addressed, with the exception of flammability. A waiver was requested for storage stability, and the corrosion characteristics test is ongoing.

CLASSIFICATION: <u>Unacceptable</u>, but upgradeable if 1) the upper certified limit for and the lower and upper certified limits for are corrected on the CSF; and 2) results of a flammability test are submitted. Results of the corrosion characteristics test must be submitted upon its conclusion.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test Material: Aloe Herbal Horse Spray (a.i., 0.75% w/w citronella oil; 0.50% w/w cedarwood oil; 0.378% w/w eucalyptus oil)

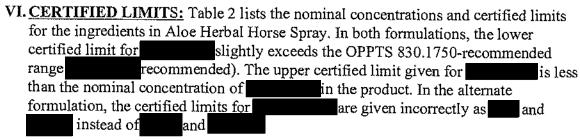
Manufac	turing process information may be entitled to confidential treatment	.*
)	
Ι.	PRODUCT IDENTITY AND COMPOSITION: Aloe Herbal Horse Spray is an end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. CSFs for a basic and an alternate formulation were provided. The active ingredients in both formulations (w/w) are 0.75% % citronella oil, 0.50% cedarwood oil (given as "cedar oil" on the CSF), and 0.378% eucalyptus oil. The inert ingredients (w/w) in the basic formulation are	
И.	<u>Description of Beginning Materials</u> : The beginning materials for the basic formulation of Aloe Herbal Horse Spray are citronella oil: cedarwood oil: eucalyptus oil;	
	MSDSs for the beginning materials were provided in MRID 47029302.	
m.	Deficiencies: None. DESCRIPTION OF FORMULATION PROCESS: Aloe Herbal Horse Spray is	
	formulated in a batch process by a simple mixing of the active and inert incredients	
	Deficiencies: None.	

IV. <u>DISCUSSION OF FORMATION OF IMPURITIES:</u> No impurities are expected to form during the formulation process or during transport and/or storage of the product.

Deficiencies: None.

V. PRELIMINARY ANALYSIS: The registrant states on p. 4 of MRID 47029302 that preliminary analysis is not required since the product is produced by a non-integrated system using a registered manufacturing use product. According to the CSF and the description of the formulation process provided in MRID 47029302, a registered manufacturing use product is not used, and the three active ingredients are not registered. However, the registrant provided certificates of analysis for five lots of the three active ingredients in MRID 47029301, which satisfies the preliminary analysis requirement.

Deficiencies: None.



Ingredients (CAS number)	PC Code	Purpose	Concent	ration (% b	y weight)
			Nominal	Lower	Upper
	Activ	ve Ingredients		<u></u>	
Citronella oil (CAS No. 8000-29-1)	021901	Active ingredient	0.75	0.675	0.825
Cedar oil (CAS No. 8000-27-9)	040505	Active ingredient	0.50	0.45	0.55
Eucalyptus oil (CAS No. 8000-48-4)	040503	Active ingredient	0.378	0.340	0.416
	Iner	t ingredients			•

^aData from CSF

<u>Deficiencies:</u> The upper certified limit for must be adjusted to a value higher than the nominal concentration of in the product. In the alternate

Inert ingredient information may be entitled to confidential treatment

formulation, the lower and upper certified limits for	must be corrected to
respectively.	

VII. ENFORCEMENT ANALYTICAL METHOD: The registrant requested a waiver of the requirement for an enforcement analytical method for each active ingredient in the product. 40 CFR 158.155(f) states that if the identity of an ingredient cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized) the registrant must provide sufficient information to enable the Agency to identify its source and qualitative composition. The registrant provided specification sheets and certificates of analysis for five lots of each active ingredient in MRID 47029301.

Each of the active ingredients in Aloe Herbal Horse Spray is an essential oil composed of a group of chemicals. In some cases, individual chemicals are an integral component of more than one of the active ingredients. The registrant provided results for a typical analysis of each of the pure essential oils in MRID 47029303. The results show that 11 of the individual chemicals are integral components of both citronella oil and eucalyptus oil. The individual analytical results for the essential oils also show that many of the individual chemicals are found only at very low concentrations in the pure oil. Since each essential oil is present at a concentration of <1% in the formulated product, many of the individual chemicals in the essential oils will be present in the product at levels below the limits of detection. For these reasons, the registrant does not believe that the end use product can be analyzed for each active ingredient.

The registrant also notes that citronella oil and cedarwood oil are classified as minimum risk pesticides under 40 CFR 152.25 (f)(1) and that ingredients in the basic formulation are List 4A inerts. Thus, approximately 82% of the formulated product qualifies as a minimum risk pesticide.

Additionally, citronella oil and eucalyptus oil are designated as GRAS by FDA, and cedarwood oil is listed as a food additive. The alcohols and terpenes of cedarwood oil are also considered GRAS by FDA. On p. 9 of MRID 47029303, the registrant states that an FDA listing is included as an attachment to the report. This attachment was not included in MRID 47029303.

Deficiencies: None.

VIII. PHYSICAL AND CHEMICAL CHARACTERISTICS:

- 1. <u>Methods</u>: The methods used to determine the physical/chemical characteristics are provided in Table 2.
- 2. <u>Results</u>: The physical/chemical characteristics of Aloe Herbal Horse Spray are provided in Table 2. A waiver for the storage stability requirement was requested based on the inability to analyze for the individual active ingredients in the product

Inert ingredient information may be entitled to confidential treatment

(see enforcement analytical method section). The corrosion characteristics study is in progress.

<u>Deficiencies:</u> To address the flammability requirement, the registrant submitted "not applicable since Aloe Herbal Horse Spray does not contain any combustible liquids." The reviewer notes that the MSDSs for all the ingredients except and give a flash point. A flammability test meeting the requirements of OPPTS 830.6315 should be conducted. Results of the corrosion characteristics testing will need to be submitted upon its completion.

TAB	LE 3. Physical and Chemical Pr	operties for Aloe Herbal Horse S	pray – Basic Formulation ^a
Guide	line Reference No./Property	Description of Result	Methods
830.6302	Color	Clear, colorless @ 25°C	CCL SOP 10.12
830.6303	Physical State	Liquid @ 25°C	CCL SOP 10.12
830.6304	Odor	Not required for EP	
830.6313	Stability	Not required for EP	
830.6314	Oxidation/Reduction: Chemical Incompatibility	No signs of reaction after 24 hrs exposure to powdered iron, potassium permanganate, water, or monoammonium phosphate	44 FR 16267
830.6315	Flammability	Not applicable, product does not contain any combustible liquids	
830.6316	Explodability	Not applicable, product does not contain any explosive ingredients	
830.6317	Storage Stability	Waiver requested	
830.6319	Miscibility	Not applicable, product is not to be diluted with petrolcum solvents	
830.6320	Corrosion Characteristics	Study in progress	
830.6321	Dielectric Breakdown Voltage	Not applicable, product not for use around electrical equipment	
830.7000	pН	4.90 @ 25°C	CCL SOP 10.17
830.7050	UV/Visible Absorption	Not required for EP	,
830.7100	Viscosity	18.266 mm ² /s (cSt) @ 22°C	ASTM Methods D 445 and D 446
830.7200	Melting Range	Not applicable, product is a liquid	
830.7220	Boiling Range	Not required for EP	
830.7300	Density/Relative Density/Bulk Density	0.8435 @ 23°C	CCL SOP 10.16
830.7370	Dissociation Constant in Water	Not required for EP	
830.7550	Partition Coefficient	Not required for EP	***************************************
830.7840	Water Solubility	Not required for EP	****
830.7950	Vapor Pressure	Not required for EP	

^a Data from MRID 47029304

IX. ADDITIONAL REVIEWER'S COMMENTS: None.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100) MRID 47029305

Prepared for Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

Prepared by Toxicology and Hazard Assessment Group Environmental Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Task Order No. 07-033

Primary Reviewer: Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature:

Date:

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Secondary Reviewer:

STUDY TYPE:

Acute Oral Toxicity - Rats (OPPTS 870.1100)

MRID NO:

47029305

DP BARCODE NO:

DP 338682

CASE NO:

Not reported

DECISION NO:

373758

TEST MATERIAL:

Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO:

21101

SPONSOR:

Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY:

Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT:

Acute Oral Toxicity Up and Down Procedure in Rats

AUTHOR:

Jennifer Durando

STUDY COMPLETED:

December 20, 2006

GOOD LABORATORY

GLP Compliant

PRACTICE:

CONCLUSION:

The oral LD₅₀ for female rats was greater than 5000

mg/kg.

CLASSIFICATION:

ACCEPTABLE -- TOXICITY CATEGORY IV

I. <u>STUDY DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients
- 2. Test Animals: Three female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, and weighed 204-231 g on the day of dosing. The young adult animals, 11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Filtered tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 19-23°C; relative humidity, 31-69%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Nos. 3101, 3102, and 3103 and were acclimated for 23 or 24 days and fasted overnight prior to dosing. The test material (5000 mg/kg body weight) was dosed by gavage (Table 1). Body weight was recorded prior to dosing, and on days 7 and 14. The test animals were observed for mortality and clinical signs of toxicity during the first several hours post-dosing and at least daily for 14 days. All animals were necropsied.

II. RESULTS:

1. Mortality: All rats survived the study.

TABLE 1. Doses, mortality/animals treated							
Dose (mg/kg)	Males	Females	Combined				
5000	-	0/3	-				

Data taken from p. 10, MR1D 47029305.

- 2. Body Weight: All rats gained weight during the study.
- 3. <u>Clinical Observations</u>: With the exception of one rat that had soft feces 3-4 hours post dosing, all rats appeared active and healthy throughout the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. <u>DISCUSSION</u>:

The oral LD₅₀ for female rats was greater than 5000 mg/kg. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE**.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (870.1200) MRID 47029306

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer: Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature

Date:

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Date:

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EPA Secondary Reviewer:

STUDY TYPE: Acute Dermal Toxicity - Rats (OPPTS 870.1200)

MRID NO: 47029306

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21102

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Acute Dermal Toxicity Study in Rats – Limit Test

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: The dermal LD_{50} for males, females, and combined was

greater than 5000 mg/kg.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test Animals: Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned to groups, and weighed 247-254 g (males) and 190-206 g (females) on the day of treatment. The young adult animals, 8-9 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 and filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 20-23°C; relative humidity, 30-70%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Male Nos. 3201 to 3205; Female Nos. 3206 to 3210. The rats were acclimated for 9 days. The test material (5000 mg/kg body weight) was applied evenly over a 2 inch x 3 inch area (approximately 10% of the body surface) on the dorsal trunk and the treatment site covered with a gauze pad. The gauze pad and entire trunk were wrapped with Durapore tape. The coverings were removed after 24 hours and excess test material removed. The test animals were observed during the first several hours after treatment for mortality, signs of gross toxicity, and behavior changes and daily thereafter for 14 days. The rats were weighed prior to treatment and on days 7 and 14. The rats were euthanized on day 14 and necropsied.

II. RESULTS:

1. Mortality: All rats survived the study.

TABLE 1. Doses, mortality/animals treated						
Dose (mg/kg)	Males	Females	Combined			
5000	0/5	0/5	0/10			

Data taken from p. 12, MRID 47029306.

- 2. <u>Clinical Observations</u>: Erythema and edema were noted at the dose site on two males and five females on days 1, 2, 3, and/or 4. All rats appeared active and healthy throughout the study.
- 3. Body Weight: All rats gained weight during the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. DISCUSSION:

The acute dermal LD_{50} for males, females, and combined was greater than 5000 mg/kg. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE**.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300) MRID 47029307

Prepared for Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

Prepared by Toxicology and Hazard Assessment Group Environmental Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Task Order No. 07-033

Primary Reviewer:

Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance:

Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature:

Date:

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Secondary Reviewer:

STUDY TYPE: Acute Inhalation Toxicity - Rats (OPPTS 870.1300)

MRID NO: 47029307

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-1, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21103

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Acute Inhalation Toxicity Study in Rats – Limit Test

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: The inhalation LC_{50} for males, females, and combined

was > 2.06 mg/L.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. <u>STUDY_DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test Animals: Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned to groups, and weighed 254-266 g (males) and 180-225 g (females) on the day of treatment. The young adult animals, 8-9 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 14-22°C; relative humidity, 30-66%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Male Nos. 3301 to 3305; Female Nos. 3306 to 3310. The rats were acclimated for 10 days prior to exposure. The animals were exposed to the concentration shown in Table 1. The rats were exposed nose-only in a Mini Nose-Only Inhalation Chamber (ADG Developments Ltd) for four hours and one minute. They were observed during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were sacrificed and necropsied on day 14.

Nominal Grav. Conc. Conc. (mg/L) (mg/L)	Grav.	Conc. (um)	GSD	Particles	Temp	Humidity	Mortality		
	1		(μm) ≤3.3 μm (%)		(°C) (%)		Male	Female	Combined
13.08	2.06	2.4-2.6	1.87- 1.90	~83	21-22	53-57	0/5	0/5	0/10

Data taken from Tables 4-6, pp. 9, 11, and 16-18, MRID 46523206.

Generation of the test atmosphere and description of the chamber: The exposure atmosphere was generated using a 1/4 inch JCO atomizer (Spraying Systems Inc.), FC3 fluid cap and AC1502 air cap (Robert Miller Associates). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional filtered compressed mixing air was supplied directly to the exposure chamber from a compressed air tank. The average total airflow was 25.6-25.9 liters/min and the nose-only exposure chamber volume was 6.7 L. Time to equilibrium was approximately 1 min.

<u>Test atmosphere concentration</u>: During exposure, gravimetric samples were collected from the breathing zone of the animals six times, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

<u>Particle size determination</u>: Particle size for each exposure concentration was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

II. RESULTS:

- 1. Mortality: All rats survived the study.
- 2. <u>Clinical Observations</u>: Clinical signs of toxicity were not reported for the period during exposure. Irregular respiration, hunched posture, moist rales, and/or hypoactivity were observed upon removal of the animals from the chamber. All animals had reduced fecal volume on Days 1 and/or 2 with recovery by Day 4 and appeared active and healthy throughout the rest of the observation period.
- 3. Body Weight: All rats gained weight during the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. <u>DISCUSSION</u>:

The inhalation LC₅₀ for males, females, and combined was > 2.06 mg/L. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

ALOE HERBAL HORSE SPRAY

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400) MRID 47029308

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:

Susan Chang, M.S.

Signature: Date:

APR 2 0 7007

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: Date:

APR 2

Robert H. Ross, M.S., Group Leader

Signature: Date:

APR 2 6 200

Quality Assurance:

Eric Lewis, M.S.

Signature:

Date:

APR 2 6 7007

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Secondary Reviewer:

STUDY TYPE: Acute Eye Irritation - Rabbits (OPPTS 870.2400)

MRID NO: 47029308

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21104

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Primary Eye Irritation Study in Rabbits

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant PRACTICE:

CONCLUSION: Corneal opacity was noted on 1/3 rabbits at 1 and 24

hours after test material instillation with resolution by 48 hours. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48

hours and on two rabbit by 72 hours. Positive

conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation. Aloe Herbal Horse Spray was

moderately irritating.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY III

I. <u>STUDY DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. <u>Test Animals</u>: Three male young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Rabbit Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 48-72%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: The rabbits were ear-tagged: Nos. 3401 to 3403 and were acclimated for 14 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for approximately one second. The left eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours and at 4 days after test material instillation.

II. RESULTS:

- 1. Mortality: All rabbits survived the study.
- 2. Ocular Lesions: Corneal opacity was noted on 1/3 rabbits at 1 and 24 hours after test material instillation with resolution by 24 hours (Table 1). Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbit by 72 hours (Table 2). Positive conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation (Table 3).

TABLE	1. Individ	lual Male	e (M) and		ea of Opac	res w/ Time :ity)	e: Cornea	(A=Dens	ity of Op	acity,	
Animal No.	1 hour		24 hours		48 h	48 hours		72 hours		4 days	
	A	В	A	В	A	В	A	В	A	В	
3401	0	4	0	4	0	4	0	4	0	4	
3402	0	4	0	4	0	4	0	4	0	4	
3403	1	1	1	1	0	4	0	4	0	4	

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris								
Score Conditions	1 hour	24 hours	48 hours	72 hours	4 days			
Conjunctiva								
Erythema	2	2	1 to 2	1	0			
Chemosis	1 to 2	l	0 to 1	0	0			
Discharge	2-3	1 to 2	0 to 1	0	0			
Iris	<u> </u>	1	0 to 1	0	0			

Irritation score is based on Draize Method

Cornea

Scale for Scoring Ocular Lesions

<u></u>	- 77
A.	Opacity-degree of density (area most dense taken for reading)
	No Opacity
	Easily discernible translucent areas, details of iris slightly obscured
	Opalescent areas, no details of iris visible, size of pupil barely discernible
	Opaque, iris invisible
R	Area of cornea involved
ъ.	One quarter (or less) but not zero
	Greater than one quarter, but less than half
	Greater than half, but less than three quarters
	Greater than three quarters, up to whole area
	Score = A x B x 5 Total Maximum Score = 80
<u>Iris</u>	
	Values
1	Normal
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination
	of any thereof), iris still reacting to light (sluggish reaction is positive)
	No reaction to light, hemorrhage, gross destruction (any or all of these)2*
	Score = A x 5 Total Maximum Score = 10
Co	niunctiv <u>ae</u>
Α.	Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)
	Vessels normal
	Vessels definitely injected above normal
	More diffuse, deeper crimson red, individual vessels not easily discernible2*
	Diffuse beefy red
В.	Chemosis
	No swelling0
	Any swelling above normal (includes nictitating membrane)
	Obvious swelling with partial eversion of lids
	Swelling with lids about half closed
	Swelling with lids about half closed to completely closed
C.	Discharge
	Any amount different from normal (does not include small amounts observed in inner canthus of
	normal animals)
	Discharge with moistening of the lids and hairs just adjacent to lids
	Discharge with moistening of the lids and hairs, and considerable area around the eye
	Score = $(A + B + C) \times 2$ Total Maximum Score = 20

^{*} represents a positive response

TABLE 3. Summary of Total ^a and Primary Eye Irritation Scores with Time							
Animal #	l hour	24 hours	48 hours	72 hours	4 days		
3401	15	13	11	2	0		
3402	15	13	4	2	0		
3403	24	20	9	2	0		
Average scores	18.0	15.3	8.0	2.0	0.0		

^aFormula: Total Irritation Score = 1 + II + III, where,

II = Iris Score = Severity x 5

III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2

III. DISCUSSION:

Corneal opacity was noted on 1/3 rabbits at 1 and 24 hours after test material instillation with resolution by 48 hours. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbit by 72 hours. Positive conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation. Aloe Herbal Horse Spray was moderately irritating and is in TOXICITY CATEGORY III. The packet classification is ACCEPTABLE.

I = Corneal Score = [Density (A) x Area (B)] x 5

^bAverage Primary Irritation = Sum of Total Irritation Scores ÷ 3

ALOE HERBAL HORSE SPRAY

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500) MRID 47029309

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:	
Susan Chang, M.S.	

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature:

Date:

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EPA Secondary Reviewer:

STUDY TYPE:

Primary Dermal Irritation - Rabbits (OPPTS 870.2500)

MRID NO:

47029309

DP BARCODE NO:

DP 338682

CASE NO:

Not reported

DECISION NO:

373758

TEST MATERIAL:

Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO:

21105

SPONSOR:

Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY:

Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT:

Primary Skin Irritation Study in Rabbits

AUTHOR:

Jennifer Durando

STUDY COMPLETED:

December 20, 2006

GOOD LABORATORY PRACTICE:

GLP Compliant

CONCLUSION:

Well defined moderate to severe erythema was noted on all rabbits 30-60 minutes after patch removal that persisted through day 14. Clearance on two rabbits was noted by day 14. Slight edema was noted on all animals 30-60 minutes after patch removal with clearance by Day

14. The primary irritation index was 3.8.

CLASSIFICATION:

ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.

2. <u>Test Animals</u>: Three female young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 46-72%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.

3. Methods: The rabbits were ear-tagged, Nos. 3501to 3503, and were acclimated for 8 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were treated with 0.5 mL of test material applied on a 6 cm² clipped intact site, and the site covered with gauze pad. The pad and entire trunk were wrapped with a semi-occlusive Micropore tape and Elizabethan collars were placed on the rabbits. The covering and the collar were removed four hours later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours and at 7, 10, and 14 days after removal of the patch.

II. RESULTS:

1. Mortality: All rabbits survived the study.

2. <u>Dermal responses</u>: Well defined erythema was noted on 2/3 rabbits 30-60 minutes after patch removal that persisted through 72 hours. The erythema reduced on one rabbit by Day 7 and persisted on one rabbit through Day 14. The third rabbit had well defined erythema 30-60 minutes after patch removal, moderate to severe erythema by 24 hours, well defined erythema at 72 hours, that reduced to very slight erythema by Day 10. The primary irritation index was 3.8.

Irritation Scores:

TABLE 1. S	ummary of indivi	dual rabbit	's dermal ir	ritation sco	res with tim	ic		
		Hours				Days		
Animal Nos.	1	24	48	72	7	10	14	
3501	2/2 ^a	2/2	2/1	2/1	I/I	1/1	1/0	
3502	2/2	2/2	2/2	2/1	1/1	0/0	0/0	
3503	2/2	3/2	2/2	2/1	1/1	1/0	0/0	

Data taken from Table 1, p. 13, MRID 47029309.

Description of rating method:

Evaluation of Skin Reaction:	Score
Erythema formation:	<u>-</u>
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema Formation:	
No edema	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised by more than 1 mm extending beyond the area of exposure)	

^aErythema/Edema

III. DISCUSSION:

Well defined erythema was noted on 2/3 rabbits 30-60 minutes hour after patch removal that reduced to very slight erythema on one rabbit through Day 7 with clearance by Day 10 and on another rabbit through Day 14. The third rabbit had well defined erythema 30-60 minutes after patch removal, moderate to severe erythema by 24 hours, well defined erythema by 48 and 72 hours, that reduced to very slight erythema by Day 10 with clearance by Day 14. Slight edema was noted on all animals 30-60 minutes after patch removal that persisted on some animals through Day 14. The primary irritation index was 3.8. Aloe Herbal Horse Spray was moderately irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE**.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG (870.2600) MRID 47029310

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer: Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature:

Date:

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Disclaimer

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EPA Secondary Reviewer:

STUDY TYPE: Skin Sensitization - Guinea Pigs (OPPTS 870.2600)

MRID NO: 47029310

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21106

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Dermal Sensitization Study in Guinea Pigs (Buehler

Method)

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: After three consecutive weekly inductions, the test

animals showed positive signs of irritation 24 and 48 hours after challenge. Aloe Herbal Horse Spray was a

dermal sensitizer.

CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN:

- 1. <u>Test material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test animals: Thirty female Hartley guinea pigs were received from Elm Hill Breeding Labs, Chelmsford, MA, were assigned to groups, and weighed 318-403 g at experiment start. The body weight was not reported for four males that were used for preliminary irritation testing. The young adult animals were housed individually in suspended stainless steel cages with mesh or plastic perforated floors. The animals were fed pelleted Purina Guinea Pig Chow No. 5025. Filtered tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 48-75%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Male and Female guinea pigs were marked with color codes and grouped: Preliminary irritation testing Nos. 3680 to 3683 (males); Test Nos. 3601 to 3620 (females); Naive Control Nos. 3621 to 3630 (females). The guinea pigs were acclimated for 7-39 days. The animals were induced and challenged according to the method of Buehler. From the results of the preliminary irritation testing, undiluted test material was used for induction and challenge. The dorsal and flank areas of 20 test guinea pigs and 10 naive control animals were clipped prior to each treatment. For the induction, 0.4 mL undiluted test material was applied to the animal using a Hill Top Chamber secured with non-allergenic adhesive tape. The chamber and excess test material were removed after six hours. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.4 mL of undiluted test material. Reactions were scored at approximately 24 and 48 hours following induction and challenge application.

II. RESULTS:

- 1. Mortality: All animals survived the study.
- 2. Body Weight: All animals gained weight during the study.
- 3. Skin Effects: Very faint usually non-confluent erythema was noted on 8/20 test animals 24 hours after the first induction with clearance on 4/12 animals by 48 hours. Very faint usually non-confluent erythema was noted on 12/20 test animals 24 hours after the second induction that persisted through 48 hours. Very faint usually non-confluent erythema and faint usually confluent erythema were noted on 11/20 and 8/20 test animals, respectively, 24 hours after the third induction and on 15/20 and 3/20 test animals, respectively, 48 hours after the third induction. Faint usually confluent erythema was noted on 11/20 test animals 24 hours after challenge and on 9/20 test animals 48 hours after challenge. Very faint usually non-confluent erythema was noted on 6/10 naive control animals 24 hours after challenge with clearance on four animals by 48 hours.

TABL	E 1. Summary of	Individual	Erythema	Challeng	e Scores wit	h Time "		<u></u>
	24 hours				48 hours			
Erythema Score	0	0.5	1.0	2.0	0	0.5	1.0	2.0
Treated	1	8	11	0	3	8	9	0
Naive Control	4	6	0	0	8	2	0	0

^{*}Number of animals affected

Evaluation score is based on Buehler Grading Scale.

Scale for Scoring Skin Reaction

Buehler sensitization scoring scale

Erythema	Score
No reaction	
Very faint, usually nonconfluent	
Faint, usually confluent	1
Moderate	
Severe with or without edema	3

III. <u>DISCUSSION</u>:

After three consecutive weekly inductions, the test animals showed positive signs of reactivity while the naive control animals showed no positive signs of reactivity 24 and 48 hours after challenge. The study included an alpha-hexylcinnamaldehyde (HCA) positive control study which was carried out within six months of the study and the results were appropriate. Aloe Herbal Horse Spray was a dermal sensitizer. The packet is classified as ACCEPTABLE.

SUPER GUARD 3535 INSECT REPELLENT

~ OPTIONAL LANGUAGE ~

NEW [claim would be valid for 6 months from the date of the first product shipment]

Sun Block With Insect Repellent

Repels (mosquitoes)(for) Up to 8 Hours

Dries Instantly ★ Waterproof ★ Pleasant Fragrance ★ DEET Free ★ SPF 30 ★ PABA Free

Contains 20% IR3535 Insect Repellent

Contains Aloe and Vitamin E to soothe and naturally moisturize skin Hypoallergenic★Non-comedogenic - won't clog pores

Waterproof & Sweatproof ★ All Day Waterproof and Sweatproof protection

(8 hour) UVA / UVB Protection

Dries Instantly - no greasy residue

Easy to use spray formula for no hassle application

Light spray gel won't drip - or cause your grip to slip

Pleasant fragrance (scent may be defined)

Suitable for the entire family (See Directions) *Quick dry waterproof spray DEET Free formula doesn't require washing off of skin upon return to indoors.

Repels mosquitoes that may (carry) (transmit) the West Nile virus (encephalitis) (diseases). Provides effective, dependable, and long lasting repellency against mosquitoes.

(Company Name) Sun Block with Insect Repellent formula provides all day waterproof SPF 30 sun protection and repels mosquitoes for up to 8 hours. Gentle formula does not need to be washed off when returning from the outdoors. Pleasant fragrance.

ACTIVE INGREDIENT:

3-((N-butyl-N-acetyl)-amino	
propionic acid ethyl ester*	20%
OTHER INGREDIENTS:	80%
TOTAL:	100%
*IR3535® Insect Repellent	

Keep Out of Reach of Children CAUTION

See back panel for additional precautionary statements.

	FIRST AID
If In Eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.
Hav	HOTLINE NUMBER e product container with you when calling for help or going for treatment. Questions ???: 800-940-4464, Weekdays from 9-5 EST.

NOTE: The First Aid statement's grid format will always be used if market label space permits; otherwise a paragraph format will be used.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS: CAUTION: For external use only. Causes moderate eye irritation. Do not get in eyes. Use on children under 6 months of age only with the advice of a physician. PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat and open flame. Contains alcohol. Avoid contact with plastics.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Apply liberally and evenly over dry, exposed skin. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes, reapply after 8 hours. For sunscreen protection, reapply after toweling off or as needed. Do not exceed 7 applications per day for adults, 3 applications per day for children.

STORAGE: Store in a cool, dry place in tightly closed container.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

ACTIVE SUNSCREEN INGREDIENTS: Octinoxate (7.5%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%). INACTIVE INGREDIENTS: acrylates/octylacrylamide copolymer, SD alcohol 40 (48.67%), aloe barbadensis leaf extract, C12-15 alkyl benzoate, fragrance, isopropyl palmitate, tocopheryl acetate.

ASSOCIATED REGISTRATIONS, P.O. Box 188; Safety Harbor, FL 34695, 1-800-356-7811 EPA Reg. No. 54287- EPA Est. 54287-FL-1 1R3535® is a registered trademark of Merck KgaA.

\$4287-XSG3535INITIAL090706-revised122606-EPA

40 CFR Part 158, Section 155, Paragraph (f)

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(f) Ingredients that cannot be characterized. If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

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Chemical Ingredients

Search Criteria: 8000-27-9

PC Code: 40505

Possible Names for this Chemical:

- · Cedarwood oil
- CAS Reg. No. 8000-27-9
- Juniperus virginiana oil

Display: • Active Registrants Only C All Registrants Get Company Info

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NPORS Public National Pesticide Information Retrieval System...

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Chemical Ingredients

Search Criteria: 8000-48-4

PC Code: 40503

Possible Names for this Chemical:

Oil of eucalyptus

• CAS Reg. No. 8000-48-4

Display: Active Registrants Only C All Registrants Get Company Info



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NP9RS Public National Pesticide Information Retrieval System...

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Chemical Ingredients

Search Criteria: 8000-29-1

PC Code: 21901

Possible Names for this Chemical:

- Oil of citronella
- CAS Reg. No. 8000-29-1
- Citronella oils
- #5562-PBA Polybeads

Display: • Active Registrants Only • All Registrants Get Company Info

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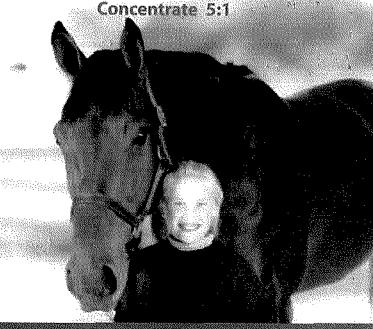
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Natural Horse Care Products

ESPREE

Aloe Herbal Horse Spray

Fly Repellent
Concentrate 5:1



Repels Flies and Other Common Insects

Contains Aloe Vera, Sunscreen and Coat Conditioners

Long Lasting Protection

32 floz (946ml)

Aloe Herbal Horse Spray

Fly Repellent

Agents offective by spare to must be used to assore the publics, grain, incorporate and other thang election to make a home a residence with contract to make a residence and letter with head underted an index.

Directions: Dilete 5 parts were in 1 pain terre spray, for more subbeniceses, dilete 4 pains water in 1 pain frees spray. To be used not including pay contained of your speak. Brush coar to remove excess distance of your speak as independent of the speak of any direction or the larger area. For their exercis, each to a use a sound. Apply with close or the larger area. Do not grip no minimate prepried for turning construction.

SHAKE WELL BEFORE EACH APPLICATION

Active Ingredients: Controlla CH Park, Economica Con 90%, Eugalgoria CM 375%;

Inert Ingledients: Wit te Missest Gr.) Executable Gr. PEG 4 cannot Extent temporary Myrotane. Also Barbadardio Leaf Uii. Coryl Methodycerography a Womeness Oxtest 175191

Caution: Keep two of reach of Children and trivial eye contact of product charge information with regar, fund proporties with water of constraint occurs observations use. Dithor trains contained and

MALE WITH BURNAN GRADE INGREDIENTS - 100% CHOCGRADABLE - ANIMAL CHIELLY FREE - NOR-TOXIC - ENVELONMENTALLY FRENDLY

Spray ddiktat et efficiala, tomosó obys impossas moscha, moschanno, polystypias et autres insocras

Mode d'emploit Diser 5 parties d'est dans 1 partie de contyntré de parénagithe patrimiserant. Pour les un plus resolutante, esterné perties a eur dans 1 parties à partie de consentré de pulvir sation pour disertier. A utiliser avec la consentre de travellment de voir entre d'inspers le delaige pour éranter l'écons de saisté et de porsoner les les consentres de pulvir sation de parties de la faction de partie de la faction de consentre de pulvir sation des parties de la faction de partie de la faction de l'éconse faur répéra de la faction de l'éconse faur réponde de la faction de la f

BIEN SECOUER AVANT CHAQUE APPLICATION

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tibridestrant repetiente suave y eficar formulado para repeter proscan i paparen impopultro y otros indectos caracines

Instrucciones: Olivra 1 particula la sociación por cubatra en 5 gartes de agra. Para cusos más difuriles, ocerant gante dona sociación configura en 4 partes de agra. Con usante con el cooperata contrador ese extende perfuer. Copille di peting para efermant el excerción sección y porve. Costango el recuperne attantivador estra 18 y 12 pulgosare del distancia Hall palles, cara logos una upicación. Fegura seguir resputador estra 18 y 12 pulgosare del distancia Hall palles, cara logos una substancia per costante entre applicación per participado seguir esta periodo entre periodo.

AGITAR 8)EN ANTES DE CADA APLICACIÓN

Ingredientes activos:

Incredientes inertes:

Advertencia: Madienga fuencial arcanda da intrados y ente al contenta con resigna. Suo procedimento en contino atmissi ordi, espringiar os rous beor con agua. Suo procedimento en contino atmissi da granda producto intrada a qualita el recipiente.

En mitt, effaktiv skriry med teaftersom och seproposer-ental harrstand fär att häna helps, anggjor och andra vanlegt insekter barra. Användning: Späd Sirlessa vatten myd. 1 per späry. Vet sänsidt svära publism späd 4 defar vatten andri 1 det spray. Använd vallin spraytisand. Boreta pullism far att avtöglisti on uta noti Hamm. Spraya da 25 t.m. håb pätten kin basta repullar. Upprega vid behay. Studda konnega områden.

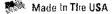
SKAKA VÄLINNAN ANVÄNONING

Aktiva ämnen: Övrist innehält:

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Manufactured By

ESPREE





Espace Anneal Products Inc. • PO Box 3650, Grapevine, TX, 70051 • Grave come com

Todd Peterson/DC/USEPA/US t0/11/2006 02:49 PM

To Catherine Rice <crice@lewisharrison.com>

cc Todd Peterson/DC/USEPA/US@EPA

bcc

Subject RE: Espree Aloe Herbal Horse Spray

Hi Cathy,

Comments gleaned right from the horses mouth (so to speak ... that's an appropriate expression don't you think so!).

Anyway, read the following for ideas and general comments. I've copied these from other e-mails so they are in the words of the individual whose name precedes the comments!

Russ

In regard to #2. in minutes: Since product is a spray, registrant will need to address exposure to non-targets if product is applied outdoors. If product is labeled to be applied only indoors (in stalls, barns, etc., there are no non-target issues.

Roger

The answer to the first question is, we would need efficacy data if the label claimed to repel public health pests.

There might be tolerance issues, but that would create the need for additional data. For example, we would need a subchronic toxicity study by the oral route for the TGAI and a developmental toxicity study with the TGAI to satisfy FQPA requirements for risk assessment (i.e., find an oral toxicity endpoint on which to base a risk characterization). We would also need to do a secondary residue study to determine the likely residues in meat and milk. These data could be waived if the registrant would be able to demonstrate no toxicity endpoints (i.e., the two tox studies show no effects at limit doses usually of t000 mg/kg/day) or show that there would be no likely residues because the a.i. would not be absorbed through the skin of treated livestock. The livestock use would open up a much more rigorous set of data requirements that would probably be very expensive and take a couple of years to complete.

Todd

Be aware that the requirement for efficacy data is a guideline requirement. We will not request that you submit the data unless it is for a human health pest. If for any reason we needed the data, we'd expect you to have it on hand. That's my understanding. In practice we don't tend to ask for the efficacy unless some situation comes up. In this case, for horses, we'd probably not ask and your market place will tell you if the product really works. If sales drop ... well ... time to develop another product!

With regard to using REDs. If you rely on data associated with a recent RED, the data may be compensable. IF a really old RED, the data may not be strong or technically good enough (just see if the RED is chiseled in stone by a cave man, that's usually a good indication of an old RED). [just kidding!]

About use ... if horses are treated in stables, barns, enclosed holding pens, then there outside ECO issues drop out of site and you may get waived based on use pattern

For cattle, etc., I'd suggest making the product for horses first, get the channel of trade up and running and then explore new uses later. If this is a small business, even under PRIA, the fees won't be much of an issue for adding new uses. If you need to develop data, it's nice to have the product selling in the mean time.

Phone call ...

If you have follow on questions give me a call Thursday. I got in really late today and am trying to catch up.

Best Regards,

Todd Peterson, Ph.D Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224



Catherine Rice <crice@lewisharrison.com> 09/25/2006 12:20 PM To Todd Peterson/DC/USEPA/US@EPA

cc Justin Jones <jjones@espree.com>

bcc

Subject Espree Aloe Herbal Horse Spray

Hi Todd,

Attached is a summary of our September 14, 2006 meeting regarding Espree Aloe Herbal Horse Spray. Rather than attach multiple documents, I have scanned this in as one .pdf file. Please let me know if you have any difficulties reading this.

As outlined in the meeting notes, there are two issues where we need clarification:

1. Does efficacy data need to be submitted?

2. If our client decides to expand the use from horses to livestock, will there be tolerance issues?

I look forward to hearing back from you on this product.

Cathy Rice Lewis & Harrison 202-393-3903 ext. 13

Pre-submission meeting notes.pdf

Pre-submission Meeting for Espree Aloe Herbal Horse Spray

A pre-submission meeting was held on Tuesday, September 14, 2006, at USEPA Potomac Yard to discuss the registration requirements for Espree Aloe Herbal Horse Spray. Meeting attendees included the following:

Fodd Peterson, EPA

Linda Hollis, EPA

Roger Gardner, EPA

Russ Jones, EPA (Via conference call)

Justin Jones. Espree (via conference call)

Bill Lindo. Espree (via conference call)

Eliot Harrison, Agent for Espree

Cathy Rice, Agent for Espree

Attached are copies of the draft label and Confidential Statement of Formula. Please note that the label will be updated based on the acute toxicology testing results.

Meeting highlights:

1. The registrant gave a brief description of the product composition and use which follow:

Proposed Product:

Aloc Herbal Horse Spray is an end-use product for use on horses (and possible other livestock including pigs, cattle, etc.)

Proposed Formulation:

Active ingredients include citronella oil, cedar oil, and eucalyptus oil All the source active ingredients are unregistered since there are no technical or MIJP registrations for these actives.

Two of the actives (citronella oil and cedar oil) are 25(b) actives. REDs have been issued for all three of these active ingredients.

Proposed Dilution Directions:

5 parts water to 1 part horse spray

For more stubborn cases, use 4 parts water to 1 part horse spray

Proposed Application Directions:

Hold spray container 10 to 12 inches away from coat for best application. Repeat as necessary. Apply with cloth to the facial area. May be used indoors or outdoor.

2. Russ Jones went through the Part 158 data requirements for the product. Active ingredients:

Since unregistered sources of the active ingredients will be used, the registrant must address all the applicable TGAl requirements for each active ingredient. This testing includes product chemistry, physical/chemical characteristics, toxicology, ecological effects, and environmental fate.

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End-use product:

Product-specific testing will be required for the physical/chemical characteristics and acute toxicology.

- 3. TGAI product chemistry requirements:
 The registrant asked whether the Certificate of Analysis would suffice for sample analysis for the TGAI. BPPD agreed that this was acceptable.
- 4. Toxicology testing on Eucalpytus oil:

 The registrant noted that repeat dose toxicology (sub-chronic and developmental toxicity) had been conducted with Eucalpytus oil to support the use on humans as an inset repellent. The registrant asked whether such studies would be required for use on animals. BPPD staff asked Espree to submit a waiver request for these studies (please refer to the waiver request attached to the Data Matrix Chatt). Roger Gardner indicated that a waiver request may be justified since the proposed product will be used at much lower rates than the human use and will only be used on animals.

5. Efficacy testing:

The registrant asked whether efficacy data needed to be submitted since only animal use was being claimed. BPPD indicated that they would need to make this decision.

6. Livestock use

Roger Gardner noted that the livestock use may require a tolerance/tolerance exemption. BPPD indicated that they would need to make this decision.

Proposed Method of Addressing the Part 158 Data Requirements:

Please refer to the attached data matrices for each of the three actives and the end-use product.

Issues needing clarification by EPA

- 1. Will the Agency need to review efficacy on Espree Aloc Herbal Horse Spray? Efficacy data is typically required for insect repellent. However, these repellents are typically for humans. In this case, the product will be used on horses. Thus, we believe that the Agency should not require that efficacy data be submitted.
- 2. The registrant is interested in possibly using this product on livestock. If they were to pursue this use, would there be tolerance issues?

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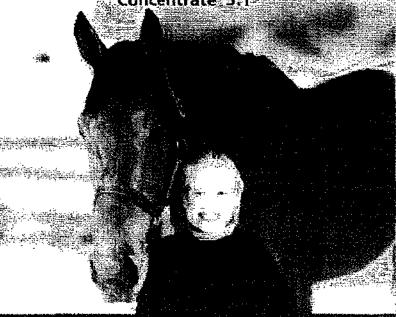
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Natural Horse Care Products

SPREE

Aloe Herbal **Horse Spray**

Fly Repellent Concentrate 5:12



Repels Flies and Other Common Insects

Contains Aloe Vera, Sunscreen and Coat Conditioners

Long Lasting Protection

32 fl.oz (946ml)

Aloe Herbal Horse Spray

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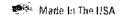
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Pages through are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Attorney-Client Privilege.
X Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



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DATA MATRIX FOR ACTIVE INGREDIENT Page f of 2 Date EPA Reg. No./File Symbol Applicant stRegistrant's Name & Address Product Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051 Aloe Herbal Horse Spray Ingredient(s); Oil of citronelta Note Guideline Reference Number Status Guideline Study Name MRID Number Submitter (1) 41785703 151B-10 - 151B-15 Product Identity, Composition, and Analysis (1) Physical/Chemical Properties 151B-17 41785703 TOXICOLOGY (1) 152B-10 **Acute Oral Toxicity** 41747402, 43179401 $\overline{(1)}$ 152B-11 41747403, 43167101 **Acute Dermal Toxicity** (1) 152B-12 Acute Inhalation Toxicity 41747404, 43167102 (1) 152B-13 Primary Eye Irritation 41747405, 43167103 (1) 152B-14 Primary Dermal Irritation 41747406, 43167104 (1) Dermal Sensitization 41747407, 43167105 152B-15 Not Applicabile 152B-16 Hypersensitivity (t) 41786701, 41785702, 152B-17 Microbial mutagenicity 41747408 Waiver Requesst (21) 152B-18 Immunotoxicity Waiver Request (22) 1528-20 90-Day oral toxici(y Waiver Request. (2) 152B-21 90-Day dermal toxicity Waiver Request (2) 152B-23 Developmental Toxicity **ECOLOGICAL EFFECTS** (1) 154B-6 Acute Avian Oral 41747409 Waiver Requesti (2) 154B-7 Avian Subacute Dietary Toxicity (1) 41747410 154B-8 Fish toxicity (1) 41747411 154B-9 Invertebrate Toxicity Waiver Requiestt ((2') 154B-10 Nomarget plants Waiver Requies;t ((2') 154B-11 Nontarget insects **ENVIRONMENTAL FATE** Waiver Request (21): ALL

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	EPA Reg. No./File Symbo	ol	Page 2 of 2
Idress: Product O Box 3650. Grapevine, TX 76051 Atoe Herbat Horse Spray			
IRID Number	Submitter	Status	Note
	RID Number	Product Atoe Herbat Horse Spr	Product Atoe Herbat Horse Spray

PODINOTES

- 1. Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been fulfilled
- 2. Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been waived.

Citronella (CAS Reg. No. 8000-29-1), OPP chemical code 021901) is covered by the Oil of Citronella RED Page 2-3 of the RED address the use profile:

Type of Pesticides – biochemical – insect and animal repellent

Use Sites:

Indoor nonfood: Animal treatment - horse-show/race/special, ponies

Indoor residential: human body/clothing white being worn (insect control); skin contact treatment, animal treatment (flea collar)

Outdoor residential, household/domestic dwelling outdoor premise use

Terrestrial non-food + outdoor residential: ornamental and/or share trees; ornamental herbaceous plants; ornamental woody shrubs and vines

Target Pests:

biling midges, biting flies, black flies, bugs, cats, deer flies, deer ticks, dogs, face flies, flies, flying insects, gnats, horn flies, horse flies, house flies. insects, mosquitoes, "no-see-ums", stable flies

Formulation Types registered:

Liquid ready to use, impregnates material, pelleted/tableted, impregnated collar/tag

Method and Rates of Application

Types of treatment: hand held sprayer, cloth wipe-on, candle, cartridge, rub-on, scent post application, sprinkle by hand, flea collar

Method and Rate: varies

Timing: as needed

Use Practice Limitations: None

The proposed product will be used a fiv repellent to be used on horses. The percent of citronella oil will be 0.75%.

n (horses); hor Rationale for Waiver Request: The use patterns addressed in the RED is includes a use that is almost identical the proposed use pattern (horses); however, this is for indoor uses and the proposed product also includes outdoor uses. Please note that the REO does include some outdoor residential uses. Based on this, we believe thiraft. the 📆 Dadequately protects this use pattern. Thus, according to the RED, the generic product chemistry, ecological effects, toxicology, and environmental fate diates requirements have either been satisfied and/or waiver.

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Do not send the form to this address. DATA MATRIX FOR ACTIVE INGREDIENT Page 1 of 2 Date EPA Reg No./File Symbol Applicant's/Registrant's Name & Address: Product Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051 A(oe Herba) Horse Spray Ingredient(s). Cedarwood oil Note Status Guideline Reference Number Guideline Study Name MRID Number Submitter (1) 61-Product Identity, Composition, and 42319001, 42101201, 62-Analysis 41549503, 42362601, 42362602, 42319002 (1) 63-Physical/Chemical Properties SATISIFIED TOXICOLOGY Waiver Requesst ((2)) 81-1 Acute Oral Toxicity Waiver Requess! (02!) 81-2 Acute Dermal Toxicity Waiver Request (2) 81-3 Acute Inhalation Toxicity Waiver Request (22) 81-4 Primary Eye Irritation Waiver Request (22) 81-5 Primary Dermal Irritation Waiver Request. (2) 81-6 Skin Sensitization Waiver Request: (2) 84-2A Gene Mutation (Ames Test) Waiver Request:: (≥)-84-2B Structural Chromosoma) Aberration Waiver Request: (2) 84-4 Other Genotoxic Effects **ECOLOGICAL EFFECTS** Waiver Requestt (12)₁ 71-1A Acute Avian Oral - Quail/Duck Waiver Requies # (20) 71-2B Avian Dietary - Quail Waiver Requies # ((2)) 72-1A Fish toxicity - Bluegill Waiver Requiesat ((2") 72-1C Fish Toxicity - Rainbow Trout Waiver Requessit ((2') 72-2A Invertebrate Toxicity **ENVIRONMENTAL FATE** Waiver Requesst (22): 835.2120/161-1 Hydrolysis

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D,	ATA MATRIX FOR ACTIV	E INGREDIENT		
Date		EPA Reg. No./File Sym	bal	Page 2 of 22.
Applicant's/Registrant's Name & Address. Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051 Aloe Herbal Horse Spra		pray		
Ingredient(s): Cedarwood oil				
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
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FOOTNOTES

- 1 Per page 20 of the Cedarwood Oil RED, the product chemistry generic data requirements have been satisfied.
- 2. Per pages 21-22 of the Cedarwood Oil RED, the ecological effects, toxicology, and environmental fate generic data can be waived.

Cedarwood oil (CAS Reg. No. 800-27-9, OPP chemical code 40505) is covered by the September 1993 Cedarwood Oil RED. Pages 2-3 of the RED address the use profile:

Type of Pesticides: repellent/feeding depressant; fungicide

Use sites: indoor residential: domestic dwellings and their contents, pets/animals (presumable cats and dogs) and their living and sleeping quarters

Target pets: fleas, moths, mildew Formulation types registered:

Ready to use spray - sprayed on animal bedding (0.48%)

Impregnated pet collar tag (0.5%)

Wood blocks (2-8%)

The proposed product will be used a fly repellent to be used on horses. The percent of Cedarwood oil will be 0.50%.

Rationale for Waiver Request: The use patterns addressed in the RED are slightly different from the proposed product's use pattern. However, both will be used comnon-humans (pets vs. horses) to repel nuisance insects (fleas and moths vs. flies). Additionally, the lowest rate covered by the RED is ready to use sprays at 0.48%... Ilm the concentrated form, Aloe Herbal Horse Spray contains 0.50% cedarwood oil. According to the product's use directions, this concentrate is then to be diluted with a minimum of 4 parts water. Thus, the end use will contain 0.129% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic product chemistry data requirements have been satisfied and the ecological effects, toxicology, and environmental fate data requirements can be waived.

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Date			EPA Reg. No./File Symbo	- L	Page 1 of 2
	cant's/Registrant's Name & Address: ee Anima) Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray		
Ingredient(s): Eucalyptus Oil					
Guideline Reference Number	Guideline Study Name	MRfD Number	Submitter	Status	Note
61- 62-	Product Identity, Composition, and Analysis				
63-	Physical/Chemical Properties			<u></u>	
TOXICOLO 81-1					Waiver Requesst; ((1)
81-2	Acute Oral Toxicity Acute Dermal Toxicity				Waiver Request; ((1)
81-3	Acute Dermai Toxicity Acute Inhalation Toxicity			-	Waiver Request. ((1)
81-4	Primary Eye Irritation				Waiver Request: 0(1)
81-5	Primary Demai Irritation	-			Waiver Requess1: Q1)
81-6	Skin Sensitization				Waiver Requesti (1)
84-2A	Gene Mutation (Ames Test)				Waiver Requessit ((1)
84-2B	Structural Chromosomal Aberration				Waiver Requessit (1)
84-4	Other Genotoxic Effects				Waiver Requestt (11)
152-11	Repeat dose (14-day)				Waiver Requestr (2)
152-23	Teratogenicity				Waiver Request: (2:)
	CAL EFFECTS				
71-1A	Acute Avian Oral – Quail/Duck	-		_	Waiver Request: (1)
71-2A	Avian Dietary – Quail	-		-	Waiver Requestt (11)
72-1A	Fish toxicity - Bluegill				Waivet Requestt (1)
72-1C	Fish Toxicity - Rainbow Trout	-		-	Warver Requesti (11)
72-2A	Invertebrate Toxicity	-		-	Waiver Request (11)
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161-1	Hydrolysis	_		-	Waiver Requæstt (†¹)

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DATA	MATRIX FOR ACTIV	E INGREDIENT	,	
Date		EPA Reg. No /File Symb	ool	Page 2 of 2º
Applicant's/Registrant's Name & Addiess: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051	Product A(oe Herbal Horse Spray			
Ingredient(s): Eucalyptus Oli				
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note

FOOTNOTES

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- Per pages 63 and 64 of the Flower and Vegetables Oils RED, the ecological effects, toxicology, and environmental fate generic data can be waived.
- 2. Waiver requested since the proposed end-use product will be for non-human use

Eucatypius oil (CAS Reg. No. 8000-48-4, OPP chemical code 40503) is covered by the December 1993 Flower and Vegetable Oils RED.

Page 7 of the RED addresses the use profile:

Type of Pesticide: repellent and insect feeding depressant

Use Sites: pets Target pests: fleas

Formulation types registered: impregnated material (collar)

Method and Rates of application

Equipment – by hand

Method and Rate - up to one ounce per animal

Timing - as needed

Use Practice Limitation: none

Product covered by RED is end-use product at 1.00%.

The proposed product will be used a fly repetient to be used on horses. The percent of Eucalyptus oil will be 0.378%.

Rationale for Waiver Request: The use pattern addressed in the RED is slightly different from the proposed product's use pattern. However, both will be used on morn-humans (pets vs. horses) to repel nuisance insects (fleas vs. flies). Further the RED covers end-use products rates at 1.00%. In the concentrated form, Aloe Herbæll Horse Spray contains 0 378% eucalyptus oil. According to the product's use directions, this product is then to be diluted with a minimum of 4 parts water. Thus, this remaid use will contain 0.095% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic ecological effects, toxicology, and environmental fate data requirements can be waived

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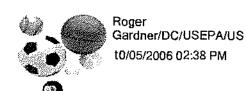
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	DATA	MATRIX FOR End	-Use Product		
Date			EPA Reg. No./File Symbol		Page 1 of 1
Applicant sfRegistrant's Name Espree Animal Products, In	8 Address: c. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray	44	
Ingredient(s): Citronetla Oit, C	edarwood Oil, Eucalyptus Oil			<u> </u>	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-	Product Identity, Composition, and Analysis		To be submitted		
63-	Physical/Chemical Properties		To be submitted		
TOXICOL	OGY				
152-10	Acute Oral Toxicity		To be submitted	-	
152-11	Acute Dermal Toxicity	-	To be submitted	-	
152-12	Acute Inhalation Toxicity	-	To be submitted	-	
152-13	Primary Eye Irritation	-	To be submitted	-	
152-14	Primary Dermal) rritation .	-	To be submitted		
152-15	Skin Sensitization	-	To be submitted	· -	
EFFICAC	Υ				
96-9	Product Performance	-	To be dete/mined	-	

FOOTNOTES		
EP	E 20	/ / / / / / / / / / / / / / / / / / /
?	*****	

	α
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Name and Title:	Date



To Todd Peterson/DC/USEPA/US@EPA

CC

bcc

Subject Re: Fw: Espree Aloe Herbal Horse Spray

Todd.

The answer to the first question is, we would need efficacy data if the label claimed to repel public health pests.

There might be tolerance issues, but that would create the need for additional data. For example, we would need a subchronic toxicity study by the oral route for the TGAI and a developmental toxicity study with the TGAI to satisfy FQPA requirements for risk assessment (i.e., find an oral toxicity endpoint on which to base a risk characterization). We would also need to do a secondary residue study to determine the likely residues in meat and milk. These data could be waived if the registrant would be able to demonstrate no toxicity endpoints (i.e., the two tox studies show no effects at limit doses usually of 1000 mg/kg/day) or show that there would be no likely residues because the a.i. would not be absorbed through the skin of treated livestock. The livestock use would open up a much more rigorous set of data requirements that would probably be very expensive and take a couple of years to complete

If you want specifics, we can spend more time on it.

Roger

Todd Peterson/DC/USEPA/US

Todd Peterson/DC/USEPA/US 10/05/2006 11:36 AM

To Roger Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA

CC Linda Hollis/DC/USEPA/US@EPA

Subject Fw: Espree Aloe Herbal Horse Spray

Russ and Roger (and Linda),

I promised to pass these documents along for our review as a follow up to the pre-registration meeting with Lewis and Harrison in conjunction with the Espree product

I have left copies [of the attachment that you'll find below] on your chair (Russ and Roger). I told Catherine Rice I'd do this today with the hope of getting any comments back by mid week next week. Late next week is fine, too. I know I'll get a call sometime late next week on this.

I have a better copy of the label which I can send to you or make a copy for you

Best Regards,

Todd Peterson, Ph.D Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224 ----- Forwarded by Todd Peterson/DC/USEPA/US on 10/05/2006 11:34 AM -----



Catherine Rice

Chemical: Citronella / Cedan werd / Evenlyphis of Date: 9/14/06
Time: 2PM

Name	Affiliation	Phone
Todd Peterron	EPA / BPPD	7-3 308 1224
ELIUT Harrum	L+H represeting Epice	102-397-3903
Roger Gardner	EPA/BPPD/BPB	703 308-8268
Cathry Rice	L: H / 19 prosenting Esp	le 202-393-3903
Linda Hollis	EPA - BPPD	703-300-9733

Individuals on Conference Line:

Russell Jones	EPA /BPPD	
Justin Jones	Espres	
Bill Lindo	Espree	
1		

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livertisk on label it food use then thanks become an irrue Dront -> 910 -2180.930 Priorie it? Chad on the label



Russell Jones/DC/USEPA/US 09/t4/2006 09:47 AM

To Todd Peterson/DC/USEPA/US@EPA

cc

bcc

Re: Pre-Registration meeting ... refresh my memory ... what Subject phone number do we use for you? I'll call you at 2PM (eom)

Todd:

The number is 304/728-4365
Russell S. Jones, Ph.D., Senior Biologist
Chair, Biochemical Classification Committee
Biochemicals Branch Science Team Captain
Biopesticides & Pollution Prevention Division (7511P)
Office of Pesticide Programs
U. S. Environmental Protection Agency
2227 South Crystal Drive
One Potomac Yard, 8th Floor
Arlington, VA 22202
Ph: 703/308-5071

Ph: 703/308-5071 FAX: 703/308-7026 jones.russell@epa.gov

Visit http://www.epa.gov/pesticides

-----Todd Peterson/DC/USEPA/US wrote: -----

To: Russell Jones/DC/USEPA/US@EPA From: Todd Peterson/DC/USEPA/US

Date: 09/14/2006 09:08AM

Subject: Pre-Registration meeting ... refresh my memory ... what phone number do we use for you? I'll

call you at 2PM (eom)

Best Regards,

Todd Peterson, Ph.D Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224

Page 96_ is not included in this copy.								
Pages through are not included in this copy.								
The material not included contains the following type of information:								
Identity of product inert ingredients.								
Identity of product impurities.								
Description of the product manufacturing process.								
Description of quality control procedures.								
Identity of the source of product ingredients.								
Sales or other commercial/financial information.								
A draft product label.								
The product confidential statement of formula.								
Information about a pending registration action.								
FIFRA registration data.								
The document is a duplicate of page(s)								
The document is not responsive to the request.								
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.								
Attorney-Client Privilege.								
X Claimed Confidential by submitter upon submission to the Agency.								
Internal Deliberative Information.								

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Halling Season and Halling

TOTON USION



Contains Aloe Vera, Sunscreen and Coat Conditioners Repels files and Other Common Inseds

Long Lasting Protection 32 fl oz (940m)

A COUNTRY TO TAKE STORY

Fly Repellent

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SHAKE WELL BEFORE EACH APPLICATION

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BIEN SECOUER AVANT CHAQUE APPLICATION

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AGITAR BIEN ANTES DE CADA APLICACIÓN

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Fly Repellent Concentrate 5:1



Contains Albe Vera, Sunscreen and Coat Conditioners Repels Files and Other Common Insects Long lessing Protection 92 il oz. (946ml)

Aloe Herbal Horse Spray

Fly Repellent

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SHAKE WELL BEFORE EACH APPLICATION

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AGITAR BIEN ANTES DE CADA APLICACIÓN

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ESPREE Manufactures By



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U.S. Environmental Protection Agency

Pesticides: Biopesticides

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Ingredient Fact Sheets
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Protectants (PIPs)

Plant Oils Fact Sheet

	Fact Sheet	Technical Doc	Products	Registrants	Regulatory Activity	FR Notices	Bibliography
_	Note: See Table for Links to Additional Information about Specific Ingredients						

SUMMARY

The plant oils described here (see Table) are complex mixtures of substances made by plants. Oils such as lemon, orange, and anise give fruits and seeds their characteristic odor and taste. The oils are used as pesticides to repel certain animals and insects, and to kill certain insects. When used as pesticides, these oils do not present any known risks to humans or the environment.

fssued: updated 7/0 t to add Methyl salicylate and mint

I. DESCRIPTION OF THE ACTIVE INGREDIENT

Plant oils are mixtures of natural substances that come from various parts of plants, such as flowers, fruits, and wood. They are responsible for the distinctive odor or flavor of the plant they come from. As examples, the different oils produced by oranges, lemons, and mustards give these foods their characteristic smell and taste. See: Table for list

Each of these plant oils is a complex mixture of chemicals that volatilize and enter the air easily.

The exact amounts and kinds of chemicals in the oils determine their characteristic odor. Many of the volatile chemicals are found in more than one type of oil.

Sometimes the chemicals in the oil, as well as the oil itself, are registered (licensed for use) as pesticide active ingredients. It is also fairly common for two or more oils to be used in the same pesticide product.

II. USE SITES, TARGET PESTS, AND APPLICATION METHODS

Use Sites: Many outdoor and indoor sites. See Table for specifics.

Uses:

- 1) Repel dogs, cats, and some wildlife such as squirrels and gophers
- 2) Repel and/or kill insects and related species such as mites and millipedes. (See Table for specifics.)

Application Methods: These oils can be applied and used as liquid sprays, crystals, gels, and pellets, and by impregnating material, such

as posts. Other variations are also used.

III. ASSESSING RISKS TO HUMAN HEALTH

No adverse effects to humans are expected from use of these substances in repellents and insecticides. Most of these oils are found in common foods, and many are approved as food flavorings by FDA. [Note: Methyl salicylate (oil of wintergreen) can be toxic in large quantities.]

IV. ASSESSING RISKS TO THE ENVIRONMENT

No risks to the environment are expected from use of these oils in pesticide products. There is some concern about exposure of birds to pellets containing oil of mustard, but the concentration of active ingredient is considered too low to cause adverse effects.

V. REGULATORY INFORMATION

See Table.

VI. REGISTRANT INFORMATION

Many companies have received registrations for pesticide products that contain plant oils.

VII. FOR FURTHER INFORMATION, CONTACT

Brian Steinwand

Biopeslicides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Phone: 703-305-7973 (or 308-8712)

Fax: 703-308-7026

e-mail: steinwand.brian@epa.gov

DISCLAIMER: The information in this Biopesticide Fact Sheet is a summary onty.

Consult the person listed above or the Biopesticides Web Site for more information.

SUMMARY OF INFORMATION FOR PLANT OILS THAT ARE PESTICIDE ACTIVE INGREDIENTS

PLANT OIL (No. of Products)	USE SITES	ACTIONS ON TARGET PESTS	OPP # (CAS #)	REGISTRATION/ REREGISTRATION (YEAR)
	Omamental plants, lawns	Repels dogs and cats	004301 (8007-70- 3)	1952 / 1993
	O rnamental plants, homes, garbage cans	{ · · [· · · · · · · · · · · · · · · ·	12 90 29 (8007-75- 8)	1972 / 1993
Canola ^b (3)	Food crops,	Kills insects	011332	1998

	ornamental plants, houseplants		(10962- 03-0)	
Castor (5)			03 160 8 (800 t-79- 4)	1947 / 1994
Cedarwood ^a (1)	Mothproofing	Repels larvae of clothes moths	040505 (800-27-9)	1960 / 1993
Citronella ^{ab} (>30)	1) Humans and their clothing, homes, outdoor areas 2) Ornamental plants, garbage dumps	t) Repels insects and ticks 2) Repels dogs and cats	02 190 1 (8000-29- 1)	1948 / 1997
Eucalyptus ^a (4)	Cats, dogs, humans and their clothing, homes	Repels mites; Repels specified insects, including fleas and mosquitoes	040 5 03 (8000-48- 4)	1948 / 1993
Jojoba ^b (2) [Note: May work as physical barrier]	All crops	Kills/repels whiteflies on all crops. Kills powdery mildew on grapes and ornamentals	0 672 00	1996
Lavandin (2)	Homes, especially closets, drawers, clothes storage containers	Repels clothes moths		1996
Lemongrass ^a (2)	Ornamental plants, garbage dumps	Repels dogs and cats	040 502 (8007-02- 01)	1962 / 1993
[Notes: Also called oil of	residential sites (induding	Repels dogs, cats, moths, beetles	0 76601 (119-36-8) RED (73kb) (PDF)	1972
Mint (1)	Ornamental plants in ponds	Kills aphids on plants	1 288 00 (8006-90-	2000

	with or without fish	(used with thyme herb)	4)	
Mustard ^a (11) [Note: Also known as allylisothio- cyanate]	Homes, ornamental plants, garbage c a ns	1) Repels dogs, cats, wildlife such as deer and raccoons 2) Repels and kills insects, spiders, centipedes, etc.	004901 (57-06-7)	1962 / 1993
Orange ^a (2)	Ornamental plants, homes, garbage dumps	Repels dogs	040517 (8008-57- 9)	1972 / 1993
Soybean ^a (2)	Food and feed crops, ornamental plants, indoor and outdoor sites	Kills mites. Kills beetles and other Insect pests	03 1605 (8 00 1-22- 7)	1959 / 1993

Notes:

- 1. This table does not necessarily describe all plant oil active ingredients.
- 2. There is more detailed information available for most of these oils:
 - ^a Reregistration Eligibility Decision document. Go to the following web site to find documents on "Flower and Plant Oils;" "Cedarwood Oil;" "Citronella" http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg
 - ^b Biopesticide Fact Sheet.

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Last updated on Wednesday, August 23rd, 2006 URL: http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_plant-oils.htm



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Citronella (Oil of Citronella) (021901) Fact Sheet

Fact Sheet	Technical Doc	Products	Registrants	Regulatory Activity	FR Notices	Bibliography
				<u> </u>		

SUMMARY

Oil of Citronella has been used for over 50 years as an insect repellent and as an animal repellent. It is found in many familiar insect repellent products: candles, lotions, gels, sprays and towelette wipes for use on clothing and people. These products repel various insects, some of which are public health pests, such as mosquitoes, biting flies and fleas. When used according to the label, citronella products are not expected to cause harm to humans, pets or the environment.

Issued: 11/99

I. DESCRIPTION OF THE ACTIVE INGREDIENT

Oil of Citronella is a volatile, liquid oil derived from dried cultivated grasses. It works by repelling animals and insects without harming or killing them. It has a distinctive odor, which repels certain animals.

II. USE SITES, TARGET PESTS, AND APPLICATION METHODS

Use Sites: Oil of Citronella is used on humans and their clothing to repel insects. In tablet or pellet form it is also used in recreational areas, outdoor household areas, and around trees and shrubs. Animal collars and tags containing citronella are used on pets and other domestic animals to repel fleas and ticks.

Target pests: Repels various specific insects including mosquitoes, black flies, fleas, and ticks.

Application Methods: Products containing Oil of Citronella are applied in various ways:

- 1. Liquid products are sprayed or applied by hand (cloth wipe-on) on skin or clothing.
- 2. Citronella is also used in solid products such as candles, cartridges, and rub-on products.
- It is used in flea collars for cats and dogs.

II. ASSESSING RISKS TO HUMAN HEALTH

In studies using laboratory animals, Oil of Citronella shows little or no toxicity. The only concern is skin irritation. Because some products are applied to human skin, EPA requires proper precautionary labeling to help assure safe use. Therefore, if used according to label instructions, citronella is not expected to pose health risks to people, including children and other sensitive populations.

Oil of Citronella has been used extensively since 1948 without any reports of adverse effects of concern.

IV. ASSESSING RISKS TO THE ENVIRONMENT

Based on laboratory animal studies, Oil of Citronella poses minimal or no risks to wildlife. Because of the low toxicity and limited uses of Oil of Citronella, it is not harmful to the environment. No adverse effects are expected for use around the home.

V. REGULATORY INFORMATION

Registered (licensed for use) in 1948.

Number of products: 31 (September 1999)

Oil of Citronella is considered so unlikely to cause harmful effects that some citronella products are exempt from the usual regulation. However, registration is required for those products that do not meet the criteria for exemption (for instance, they contain other ingredients that EPA has not classified as minimal risk).

VI. PRODUCTS FOR USE AGAINST PUBLIC HEALTH PESTS

EPA defines a public health pest as any organism that can cause or transmit human disease, or can cause human discomfort or injury. Examples include fleas, mosquitoes, ticks, and biting flies. To help protect the publicÂ's health, EPA requires registrants of products used against public health pests to prove the product meets specific standards for effectiveness as well as for safety. The products currently registered with Oil of Citronella as the active ingredient for use against public health pests, such as mosquitoes, ticks and fleas, have met the applicable standards.

VII. PRODUCER INFORMATION

Many companies produce Oil of Citronella and products containing Oil of Citronella.

VII. FOR FURTHER INFORMATION CONTACT

Brian Steinwand
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Phone: 703-305-7973 (or 308-8712)

Fax: 703-308-7026

e-mail: steinwand.brian@epa.gov

DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only.

Publications | Glossary | A-Z Index | Jobs

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Last updated on Tuesday, May 2nd, 2006 URL: http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_021901.htm

·
Page is not included in this copy.
Pages 106 through 116 are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
X The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA PACKAGE BEAN SHEET

Date: 04-Apr-2007 Page t of 3 Decision #: 373758

DP #: (338682)

PRIA

Parent DP#:

* * * Registration Information * * *

Registration:	66963-I - ALOE I	<u>HERBAL HORSE SPRA</u>	<u> </u>				
Company:	66963 - ESPREE AN	IMAL PRODUCTS, INC					
Risk Manager:	RM 9t - Driss Benmh						
Risk Manager Reviewer:	Todd Peterson TPET						
Sent Date:	Calculated Due Date: 14-Jun-2007 Edited				Due Date:		
Type of Registration:	Product Registration - Section 3						
Action Desc:	(B67) NEW PRODUCT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;						
Ingredients:	See page 3	-					
	*	* * Data Package In	formation *	**			
Expedite:	Yes ● No	Date Ser	nt: 04-Apr-2007		Due Back:		
DP Ingredient:	See page 3						
DP Title:	: Product Chem and Tox 6 Pack						
CSF Included:	● Yes ○ No	Label included: Yes (No Pare	ent DP #:			
Assigned To	<u>.</u>	Date in	Date Out	-			
Organization: BPPD	/BPB			_ Last Possible Science	Due Date: t4-Feb-2007		
Team Name:			<u></u>	Science	Due Date:		
				Sub Dala Package	Due Date:		
				_			

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product chemistry and Tox six pack for old active ingredients in new end use product. Please review data packages attached, CSF and related label language in relation to submitted data. Todd Peterson 703-308-7224

Request for Work (Administrative)

E.P.A. Name (please circle): HED, BPPD, Antimicrobials, AEGL or FDA

Toxicology and Hazard Assessment Reviewer's Name: Lewis

Assignment No. (if available): 07-033

Location of file: N:\derrpt\\ | \ellowis \quad \quad

Please attach a copy of the work assignment form to this form before giving me your documents. Files should be copied to the N: drive in your directory.

BPPD WORK ASSIGNMENT #07-033 ORNL IAG #89939652-01 Date Mailed: April 10, 2007

PRIA Due Date: April 30, 2007

- 1. Oak Ridge National Laboratory (ORNL) shall independently review the studies identified below and prepare for each study a Data Evaluation Record (DER). In addition to its scientific expertise, the ORNL shall use the appropriate OPP Test Guidelines, science policy documents and other guidelines and materials provided to ORNL for the purpose of training, orientation and guidance concerning the preparation of DERs under the IAG.
- 2. For technical/scientific questions that cannot be resolved by the ORNL without input from BPPD science staff, the ORNL shall contact:
 - 3. MRIDs and Studies for this work assignment are as follows Todd Peterson 305-7224

EPA Reg. No.

66963-I

Product Name:

Aloe Herbal Horse Spray

Ingredients:

Company:

Espree Animal Products

Company: DP Barcode	MRID#	Study Type	Est. Hours	_ ^
338682	470293-01-02-03-94	Product chemistry	30-40	Enc
	470293-05-06-07-08-09- 10	Toxicology	30	SUSON
Total Est. Hours	NO -04		60	

Transmittal dates for the First Draft of the DERs to BPPD shall conform generally to the AWorking Days@ specified in ORNL Proposal #1834-S511-A1. The Work Assignment Manager will review the proposed Transmittal and Due Dates and negotiate a mutually acceptable schedule for EPA and ORNL for delivering the first draft of the DERs. For research reports that do not include estimated hours, please notify the Work Assignment Manager with and questions or hour estimates.

Request for Work (Administrative):
E.P.A. Name (please circle): HED, BPPD, Antimicrobials, AEGL or FDA
Toxicology and Hazard Assessment Group Reviewer's Name: Chang
Assignment No. (if available):
Location of file: N:\derrpt\chang\ \(\) \
Due date: (PLEASE CHECK WITH BOB FOR PRIORITY DATE)
Charge Account: 7240 7241 7239 7244 1151 (1392)
Confidential Statement included: yes no

Please attach a copy of the work assignment form to this form before giving me your documents. Files should be copied to the N: drive in your directory.

JUN-8 2007 Notes T. Peterson

CSF & Product Chemistry

- 1) the upper certified limit for and the lower and upper certified limits for must be corrected on the CSF;
- 2) results of a flammability test must be submitted BPPD Chemist is looking at the CSF to determine if this is required and an answer will be obtained by Friday June 8, 2007.
- 3) results of the corrosion characteristics must be submitted.

[The waiver requests for enforcement analytical method and storage stability study are acceptable.]

LABEL

The Agency recommends ordering your product's label information as follows:

Generally the following can be placed on Page 1:

Product name

Claim (Repels Flies, Gnats, and Mosquitoes)

Ingredients Statement

(Product contains: optional ingredients listing, for example: Aloe, sunscreen, and conditioners))

Keep Out Of Reach of Children

Signal Word

First Aid section

Registration Number and Establishment Number

Net Content

Company mane, Address, Phone Number

Page 2 and following pages:

Precautionary Language Environmental Hazards General Information Directions for Use Storage and Disposal section Warranty

Issues specific to your label language are as follows:

- 1. There are two lines under the product name that are redundant and can be combined. The two statements "Fly Repellent" and "Repels Flies, Gnats, and Mosquitoes" can be combined into a single product claim.
- 2. The statement "1:5 Concentrate" may confuse end users. The original label shown to the Agency at the pre-registration meeting says "Concentrate 5:1." The Agency suggests placing the word "Concentrate" just after the product name and then allow users to read how to dilute the concentrate when reading the directions for use.
- 3. Ingredients Statement: Please align listed percentages by the decimal point.
- 4. On page 2 in the first paragraph you state "effective" and "long lasting" to characterize the product's performance. The Agency has no product performance data from you to support these statements. The end user has no means to understand what "effective" and "long lasting" means. Further, the directions for use do not indicate how often the product needs to be applied.

Unless and until you submit data to indicate how long the product lasts, the label cannot use these claims.

- 5. Delete "Made with human grade ingredients." This is a potentially false or misleading statement.
- 6. Spray containers may vary from hand held sprayers to larger spray units that may be available to the end user. The Agency recommends that the label be more detailed in this regard. In relation to the direction to hold the spray container 10 to 12 inches from the coat, do you intend the product to be misted or to drench the fur of the horse? If a mist or a drench, to so stipulate will allow the end user to know they have provided sufficient coverage no matter what differences there may be when using different types of spray containers.
- 7. How does one determine a case when the pest pressure is a "more stubborn case," as indicated in the dilution directions? Perhaps stating "When pest pressure is high, use a dilution of 4 parts water to 1 part Aloe Herbal Horse Spray."
- 8. First Aid: Reorder by moving If in eyes to top. Add hotline number as per LRM.

ALOE HERBAL HORSE SPRAY Fly Repellent 1:5 Concentrate (Repels Flies, Gnats and Mosquitoes Contains Aloe Vera, Sunscreen and Coat Conditioners 32 Fl oz. (946 ml) Active Ingredients: Citronella Oil 0/75% Cedarwood Oil 0/50% Eucalyptus Oil 0.378% Other Ingredients: 98.372% TOTAL: 100% KEEP OUT OF REACH OF CHILDREN **CAUTION** See back panel for additional precautionary statements. Ano hered EPA Reg. No. 66963-I EPA Est. No.: 66963-TX-001

Net Content

ALOE HERBAL HORSE SPRAY

Moretner on Epic

A gentle, effective blend of natural botanical oils to repel flies, gnats, mosquitoes and other flying insects on horses. Contains coat conditioners and sunscreen which promote a healthy coat and protection from the sun. Made with human grade ingredients, Aloe Herbal Horse Spray provides your horse long lasting protection.

? Prod Petermana

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SHAKE CONTIANER BEFORE EACH APPLICATION.

General Directions: Apply in a covered area (i.e., stalls, barn, etc.). Brush coat to remove excess dirt and dust. For best results apply to a clean horse.

Dilution Directions: To be used in a clean spray container of your choice. Dilute with 5 parts water to 1 part horse spray. For more stubborn cases, dilute 4 parts water to 1 part horse spray.

Application Directions: Hold spray container 10 to 12 inches from coat for best

Application Directions: Hold spray container 10 to 12 inches from coat for best application. Apply with cloth to facial area. Do not use on animals intended for human consumption.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store only in a cool, dry area inaccessible to children and pets. Keep container tightly closed when not in use.

PESTICIDE DESPOSAL: Wastes resulting from use of this product may be used on site or at an approved waste disposal facility.

CÜNTAINER DISPOSAL:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 800-CLEANUP for disposal instructions.

Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

•		FIRST AID roduct container or label with you when calling a poison control center or doctor, or going for treatment.
r	If on skin:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
<u></u>	If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for further treatment advice.

Mare to be !

Manufactured By: Espree Animal Products, Inc. 3250 Stone Myers Parkway Grapevine, TX 76051

www.espree.com

1-800-328-1317

Page is not included in this copy.
Pages 126 through 127 are not included in this copy.
The material not included contains the following type of information:
X Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



Nina Simeonova/DC/USEPA/US 06/07/2007 04:40 PM

To Todd Peterson/DC/USEPA/US@EPA

CC

bcc

Subject 66936-

Todd.

The PC Codes of all the ingredients are written down.

About the tolerance exemptions:

No data is found for: Citronella Oil and Cedarwood Oil (List 25f), Aloe Vera,

probably because these are inerts not used in food

have tolerance exemptions under 180.910. There is tolerance

exemption especially for Eucalyptus Oil in 40CFR180,1241 and for

The inert

The added in the afternate formulation inert ingredients

have tolerance

exemptions under 180.910 and 180.930. The condition that the total amount of the dyes cannot exceed is fulfilled.

I found data about the Flash Point of no data are required for Box 9.

to be above 150F, so

A small mistake in the name of the sunscreen - it must be

Also, the results from search the obsolete Lists of Inert Ingredients are misplaced in Column 12 of the CSF. Moreover, they are not needed and are not even correct. The

I think that is all you wanted to know. I'm leaving the CSF on your shelf in the file room. Tomorrow I will use my personal day, so if necessary, you will see me Monday.

Have a nice weekend. Nina

Todd Peterson/DC/USEPA/US 06/08/2007 10:57 AM

To "Christina Swick" <cswick@lewisharrison.com>

CC

bcc Todd Peterson/DC/USEPA/US

Subject RE: Aloe Herbal Horse Spray (File Symbol No. 66963-1)

Hi Christina,

First, thanks much for the electronic documents. I've printed these and will look at them shortly.

Second, I apologize for one item I now see that I did not mention on the phone. For the CSFs, the suppliers should, as best can be, provided with a full address including street. Several of these have the wording "commodity item" in column 11 which is not part of an address. I suggest deleting these words.

A small mistake in the name of the sunscreen - it must be

Also, please delete the information provided in column 12. This column is used to list registration numbers when a registered source is used for an ingredient.

Third, my chemist left me comments on the CSFs. One comment that concerns me is that a surfactant listed on the CSF is revoked. I am not certain if this is in relation to food use or is not approved for any pesticide use. I will need to get clarification on Monday. I still have a question about the requirement of a flammability study. I did get some helpful information from the chemist with regard to the product flash point, but I need to clarify this in relation to what is stated in the review.

Consider this an update and I'll follow with a more interim status report for today.

Monday I have an important meeting from 1 to 3 PM and thus would like to get final word to you on any last minute issues by about 11 AM-11:30 AM.

I'm thinking of coming in on Tuesday, my usual work at home day, to wrap this up so we can have closure by Wednesday. That's the plan!

Best Regards,

Todd Peterson, Ph.D. Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224



"Christina Swick" <cswick@lewisharrison.com>

To Todd Peterson/DC/USEPA/US@EPA

CC

06/07/2007 10:59 AM

bcc

Subject RE: Aloe Herbal Horse Spray (File Symbol No. 66963-I)

History:

This message has been replied to.

Todd,

Attached is the revised label and CSFs per our discussion. I can be reached on Friday and Monday by email or cell phone (301-775-5670).

Thanks, Christina

----Original Message----

From: Peterson.Todd@epamail.epa.gov [mailto:Peterson.Todd@epamail.epa.gov] Sent: Tuesday, June 05, 2007 3:37 PM

To: Christina Swick

Subject: Re: Aloe Herbal Horse Spray (File Symbol No. 66963-I)

Hi.

Is there any chance that the company had data reviewed by the State of California?
That would be great.

Also, if the company doesn't want to hold off, we could just have them delete mosquitoes from the label.

If data come in later, we could add mosquitoes to the label. The mock up label as presented in the pre-registration meeting simply stated "Fly Repellent."

I'm going to leave in about an hour to go over to DC. I'll be in meetings most of the morning tomorrow. But I'll try to give a call when I first get in around 9 AM tomorrow.

Best Regards,

Todd Peterson, Ph.D, Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224







66936-8.BasicCSF, 20070607.pdj 66936-8.AlternateCSF, 20070607.pdj 66936-8. 20070607. ProductLabel.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE:

May 26, 2007

SUBJECT:

Section 3 Registration of Aloe Herbal Horse Spray (EPA Reg. #: 66963-I),

Containing 0.75% Citronella oil, 0.50% Cedarwood oil, and 0.378% Eucalyptus oil (Active Ingredients). Review of Product Chemistry and

Acute Toxicity.

DP No.: 338682

Decision No.: 373758

470293-10

PC Codes: 021901, 040505,

MRID Nos.:

470293-01 1hrough

011550

EPA Reg. No.: 66963-1

Chemical Class: Biopesticide

FROM:

Manying Xue, Chemist

BPB/BPPD (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 05/25/2007

BPB/BPPD (7511P)

TO:

Todd Peterson, Regulatory Action Leader

BPB/BPPD (7511P)

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED:

On behalf of Rhodia Inc., Lewis & Harrison Consultants has submitted an application for a Section 3 registration of Aloe Herbal Horse Spray containing 0.75% Citronella oil, 0.50% Cedarwood oil, and 0.378% Eucalyptus oil (Active Ingredients). Aloe Herbal Horse Spray is an end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses.

In support of this petition, the petitioner has submitted product chemistry studies of Aloe Herbal Horse Spray at nominal concentration of 0.75% citronella oil, 0.50% cedarwood oil (as "cedar oil" on the CSF), and 0.378% eucalyptus oil of the active ingredients (MRIDs 470293-01 through 470293-04), basic Confidential Statements of Formula

Aloe Herbal Horse Spray (L. A Reg. No.:66963-I)

DP Number: 338682
PC Codes: 021901, 040505 & 011550 (Citronella oil, Cedarwood oil & Eucalyptus oil)

(CSFs, dated 01/04/07), proposed labels, and acute toxicity studies for Aloe Herbal Horse Spray (MRIDs: 470293-05 through 470293-10).

BPPD has reviewed and evaluated the submissions for Aloe Herbal Horse Spray. The decisions are made to reflect the current OPP's policies.

RECOMMENDATIONS AND CONCLUSIONS:

- 1. The submitted product chemistry study for Aloe Herb Horse Spray is

 Unacceptable based on OPPTS guidelines 830 Series, but upgradeable if 1) the
 upper certified limit for and the lower and upper certified limits for
 are corrected on the CSF; 2) results of a flammability test are
 submitted; 3) results of the corrosion characteristics and flammability tests must
 be submitted. The waiver requests for enforcement analytical method and storage
 stability study are acceptable.
- 2. The submitted Tier I toxicity studies are Acceptable; no additional data are required.
- 3. The submitted label for the end-use product (aloe herbal horse spray (EPA Reg. #: 66963-I) is Unacceptable. The registrant needs to provide information for physical and chemical hazards and clarify the meaning of "human grade ingredients" in the first paragraph.
 - 4. Aloe Herbal Horse Spray, the EP, is proposed to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. Therefore there will be no Adverse Effect (NAE) on Threatened and Endangered Species.
 - 5. No product performance study has been submitted with this application. The registrant must submit product performance study for this registration.

STUDY SUMMARIES

Product Properties (OPPTS 830 Series GLNs)

End Use Product, Aloe Herbal Horse Spray

On behalf of Rhodia Inc., Lewis & Harrison Consultants has submitted an application for the Section 3 registration of aloe herbal horse spray. In support of this petition, the petitioner has submitted product chemistry studies of the end use product, aloe herbal horse spray (MRIDs 47029301 through 4702904), and basic Confidential Statements of Formula (CSFs), dated 01/04/2007 (Table 1).

Page 2 of 6

Aloe Herbal Horse Spray (L. A Reg. No.:66963-1)

PC Codes: 021901, 040505 & 011550 (Citronella oil, Cedarwood oil & Eucalyptus oil)

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
	Acti	ve Ingredients		<u> </u>	
Citronella oil (CAS No. 8000-29-1)	021901	Active ingredient	0.75	0.675	0.825
Cedar oil (CAS No. 8000-27-9)	040505	Active ingredient	0.50	0.45	0.55
Eucalyptus oil (CAS No. 8000-48-4)	040503	Active ingredient	0.378	0.340	0.416

^aData from CSF

Physical and Chemical Characteristics

The product chemistry data base for aloe herbal horse spray is essentially complete. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 2.

Aloe Herbal Horse Spray is an end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. CSFs for a basic and an alternate formulation were provided. The active ingredients in both formulations (w/w) are 0.75% citronella oil, 0.50% cedarwood oil, and 0.378% eucalyptus oil. The inert ingredients

•	(W/W) in the basic formulation are
1	inert ingredients. Adequate descriptions of the beginning materials were provided. The
	product is formulated by a simple blending of the active and inert ingredients, and no
i	impurities are formed. Results of a preliminary analysis were not provided. In both
	formulations, the upper certified limit given for
(concentration of the certified in the product. In the alternate formulation, the certified

Aloe Herbal Horse Spray (£r A Reg. No.:66963-I)

PC Codes: 021901, 040505 & 011550 (Citronella oil, Cedarwood oil & Eucalyptus oil)

limits given for the requirement of an enforcement analytical method. The physical and chemical characteristics were adequately addressed, except the study of flammability. A waiver was requested for storage stability, and the corrosion characteristics test is ongoing.

Guide	line Reference No./Property	Description of Result	Methods
830.6302	Color	Clear, colorless @ 25°C	CCL SOP 10.12
830.6303	Physical State	Liquid @ 25°C	CCL SOP 10.12
830.6304	Odor	Not required for EP	······································
830.6313	Stability	Not required for EP	
830.6314	Oxidation/Reduction: Chemical Incompatibility	No signs of reaction after 24 hrs exposure to powdered iron, potassium permanganate, water, or monoammonium phosphate	44 FR 16267
830.6315	Flammability	Need to be conducted	
830.6316	Explodability	Not applicable, product does not contain any explosive ingredients	
830.6317	Storage Stability	Waiver requested	
830.6319	Miscibility	Not applicable, product is not to be diluted with petroleum solvents	
830.6320	Corrosion Characteristics	Study in progress	
830.6321	Dielectric Breakdown Voltage	Not applicable, product not for use around electrical equipment	
830.7000	рН	4.90 @ 25°C	CCL SOP 10.17
830,7050	UV/Visible Absorption	Not required for EP	
830.7100	Viscosity	18.266 mm ² /s (cSt) @ 22°C	ASTM Methods D 445 and D 446
830.7200	Melting Range	Not applicable, product is a liquid	
830.7220	Boiling Range	Not required for EP	
830.7300	Density/Relative Density/Bulk Density	0.8435 @ 23°C	CCL SOP 10.16
830.7370	Dissociation Constant in Water	Not required for EP	
830,7550	Partition Coefficient	Not required for EP	
830.7840	Water Solubility	Not required for EP	
830.7950	Vapor Pressure	Not required for EP	

^a Data from MRID 47029304

PC Codes: 021901, 040505 & 011550 (Citronella oil, Cedarwood oil & Eucalyptus oil)

CLASSIFICATION: UNACCEPTABLE, but **upgradeable.** To upgrade to acceptable, the registrant must resolve the deficiencies described in Conclusion 1 above. The waiver requests for enforcement analytical method and storage stability study are acceptable.

Acute Toxicity (OPPTS 870.1100 - 1300 & 870.2400 - 2600)

On behalf of Rhodia Inc., Lewis & Harrison Consultants has submitted acute toxicity studies(MRIDs: 470293-05 through -10) for Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil (active ingredients) as test material for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity and skin sensitization studies. The studies were conducted at Product Safety Laboratories, Dayton, NJ. The data are summarized in the Table below. Details of the studies may be found in the attached DERs.

TABLE 3	Acute Toxicity Pro	file - Test Su	ostance	
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	47029305	$LD_{50} = >5000 \text{ mg/kg}$	1V
870.1200	Acute dermal [rat]	47029306	LD ₅₀ = >5000 mg/kg	IV
870.1300	Acute inhalation (rat)	47029307	The initialation LC ₅₀ for males, females, and combined was > 2.06 mg/L.	IV
870.2400	Acute eye irritation [rabbit]	47029308	The maximum average score was 18.0 at one hour after test material instillation. Aloe Herbal Horse Spray was moderately irritating.	111
870.2500	Acute dermal irritation [rabbit]	47029309	The primary irritation index was 3.8	111
870.2600	Skin sensitization [guinea pig]	47029310	Aloe Herbal Horse Spray was a dermal sensitizer	a dermal sensitizer

CLASSIFICATION: ACCEPTABLE; no additional data are required.

Product Performance (Nonguideline)

No product performance study has been submitted with this application. The registrant must submit product performance study for this registration.

Non-Target Organisms and Endangered Species Assessment

Aloe Herbal Horse Spray, the EP, is proposed to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. Therefore there will be no exposure to non-target organisms and No Adverse Effects (NAE) on Threatened and Endangered Species.

cc: D. Benmhend, R. S. Jones; BPPD Chron File; OHAD/ARS M. Xue, BPPD, 05/26/07

CITRONELLA OIL
CEDARWOOD OIL
EUCALYPTUS OIL
(Aloe Herbal Horse Spray)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1100)

Description of Beginning Materials (OPPTS 830.1200)

Description of Formulation Process (OPPTS 830.1200)

Discussion of Formation of Impurities (OPPTS 830.1400)

Preliminary Analysis (OPPTS 830.1700)

Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800)

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 47029301-47029304

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 07-033

Primary Reviewer:	
Eric B. Lewis, M.S.	Signature:
	Date:
Secondary Reviewers:	
Sylvia Milanez, Pl.D., D.A.B.T.	Signature:
	Date:
Robert H. Ross, M.S., Group Leader	Signature:
,	Date:
Quality Assurance:	
Lee Ann Wilson, M.A.	Signature:
	Date:
	•

Disclaimer

This review may have been altered subsequent to the contractor=s signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Secondary Reviewer: Manying Xue, Chemist, 05/26/2007 W

STUDY TYPE: Product Identity and Composition (OPPTS 830.1100)

Description of Beginning Materials (OPPTS 830.1200)
Description of Formulation Process (OPPTS 830.1200)
Discussion of Formation of Impurities (OPPTS 830.1400)

Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750)

Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-

830.7950)

MRID NO: 47029301-47029304

DECISION NO: 373758
DP BARCODE: DP338682

TEST MATERIAL: Aloe Herbal Horse Spray (a.i., 0.75% w/w citronella oil; 0.50%

w/w cedarwood oil; 0.378% w/w eucalyptus oil)

PROJECT STUDY NO: MRID 47029301 - 47029303: Not provided

MRID 47029304: Study No. 3660-01

SPONSOR: Espree Animal Products, Inc., 3250 Stone Myers Parkway,

Grapevine, TX 76051

TESTING FACILITY: MRIDs 47029301 - 47029303: None

MRID 47029304: Case Consulting Laboratories, Inc., 622 Route

Ten, Whippany, NJ 07981

TITLE OF REPORT: MRID 47029301: Aloe Herbal Horse Spray: Product Identity and

Composition. Source Active Ingredients

MRID 47029302: Aloe Herbal Horse Spray: Product Identity and

Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified

Limits.

MRID 47029303: Aloe Herbal Horse Spray: Waiver Request for

Enforcement Analytical Method and Storage Stability

MRID 47029304: Physical and Chemical Characteristics of Aloe

Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density

AUTHORS: MRIDs 47029301 - 47029303: Lewis & Harrison, LLC

MRID 47029304: Sinning, D.J.

STUDY COMPLETED: MRIDs 47029301 - 47029303: January 3, 2007

MRID 47029304: November 28, 2006

GOOD LABORATORY MRID 47029301: A signed and dated GLP statement was

PRACTICE: included. The report is a discussion of product identity of the

source active ingredients. The information was provided to the registrant, and the registrant does not know if GLP standards

were used.

MRID 47029302: A signed and dated GLP statement was included. The report is a discussion and GLP standards do not

apply.

MRID 47029303: A signed and dated GLP statement was included. The report is a waiver request, and GLP standards do not apply.

MRID 47029304: A signed and dated GLP statement was included. The study was conducted in compliance with GLP standards. The test substance stability, synthesis, and characterization are held by the sponsor, and the performing laboratory does not know if these data conform to GLP standards.

CONCLUSION:

Aloe Herbal Horse Spray is an end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. CSFs for a basic and an alternate formulation were provided. The active ingredients in both formulations (w/w) are 0.75% citronella oil, 0.50% cedarwood oil, and 0.378% eucalyptus oil. The inert ingredients (w/w) in the basic

ingradients. Adequate descriptions of the Larianian and its

ingredients. Adequate descriptions of the beginning materials were provided. The product is formulated by a simple blending of the active and inert ingredients, and no impurities are formed. Results of a preliminary analysis were not provided. In both formulations, the upper certified limit given for the interproduct. In the nominal concentration of the interproduct. In the alternate formulation, the certified limits given for the are incorrect. A waiver was requested for the requirement of an enforcement analytical method. The physical and chemical characteristics were adequately addressed, with the exception of flammability. A waiver was requested for storage stability, and the corrosion characteristics test is ongoing.

CLASSIFICATION:

Unacceptable, but upgradeable if 1) the upper certified limit for and the lower and upper certified limits for are corrected on the CSF; and 2) results of a flammability test are submitted. Results of the corrosion characteristics test must be submitted upon its conclusion.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

<u>Test Material</u>: Aloe Herbal Horse Spray (a.i., 0.75% w/w citronella oil; 0.50% w/w cedarwood oil; 0.378% w/w eucalyptus oil)

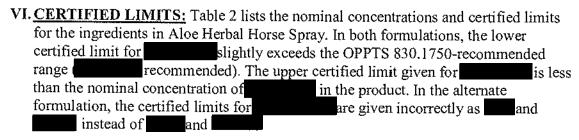
Inert ingredient information may be entitled to confidential treatment *Manufacturing process information may be entitled to confidential treatment* PRODUCT IDENTITY AND COMPOSITION: Aloe Herbal Horse Spray is an I. end use product intended to be used to repel flies, gnats, mosquitoes, and other flying insects on horses. CSFs for a basic and an alternate formulation were provided. The active ingredients in both formulations (w/w) are 0.75% citronella oil, 0.50% cedarwood oil (given as "cedar oil" on the CSF), and 0.378% eucalyptus oil. The inert ingredients (w/w) in the basic formulation are Deficiencies: None. II. <u>DESCRIPTION OF BEGINNING MATERIALS:</u> The beginning materials for the basic formulation of Aloe Herbal Horse Spray are citronella oil; cedarwood oil; eucalyptus oil; MSDSs for the beginning materials were provided in MRID 47029302. Deficiencies: None. III. <u>DESCRIPTION OF FORMULATION PROCESS</u>: Aloe Herbal Horse Spray is formulated in a batch process by a simple mixing of the active and inert ingredients Deficiencies: None. IV. DISCUSSION OF FORMATION OF IMPURITIES: No impurities are expected to form during the formulation process or during transport and/or storage of the product.

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Deficiencies: None.

V. PRELIMINARY ANALYSIS: The registrant states on p. 4 of MRID 47029302 that preliminary analysis is not required since the product is produced by a non-integrated system using a registered manufacturing use product. According to the CSF and the description of the formulation process provided in MRID 47029302, a registered manufacturing use product is not used, and the three active ingredients are not registered. However, the registrant provided certificates of analysis for five lots of the three active ingredients in MRID 47029301, which satisfies the preliminary analysis requirement.

Deficiencies: None.



Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
30.00	Acti	ve Ingredients			
Citronella oil (CAS No. 8000-29-1)	021901	Active ingredient	0.75	0.675	0.825
Cedar oil (CAS No. 8000-27-9)	040505	Active ingredient	0.50	0.45	0.55
Eucalyptus oíl (CAS No. 8000-48-4)	040503	Active ingredient	0.378	0.340	0.416
	Iner	t ingredients			

^aData from CSF

<u>Deficiencies:</u> The upper certified limit for must be adjusted to a value higher than the nominal concentration of the limit for must be adjusted to a value in the product. In the alternate

formulation, the lower and upper certified limits for must be corrected to respectively.

VII. ENFORCEMENT ANALYTICAL METHOD: The registrant requested a waiver of the requirement for an enforcement analytical method for each active ingredient in the product. 40 CFR 158.155(f) states that if the identity of an ingredient cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized) the registrant must provide sufficient information to enable the Agency to identify its source and qualitative composition. The registrant provided specification sheets and certificates of analysis for five lots of each active ingredient in MRID 47029301.

Each of the active ingredients in Aloe Herbal Horse Spray is an essential oil composed of a group of chemicals. In some cases, individual chemicals are an integral component of more than one of the active ingredients. The registrant provided results for a typical analysis of each of the pure essential oils in MRID 47029303. The results show that 11 of the individual chemicals are integral components of both citronella oil and eucalyptus oil. The individual analytical results for the essential oils also show that many of the individual chemicals are found only at very low concentrations in the pure oil. Since each essential oil is present at a concentration of <1% in the formulated product, many of the individual chemicals in the essential oils will be present in the product at levels below the limits of detection. For these reasons, the registrant does not believe that the end use product can be analyzed for each active ingredient.

The registrant also notes that citronella oil and cedarwood oil are classified as minimum risk pesticides under 40 CFR 152.25 (f)(1) and that ingredients in the basic formulation are List 4A inerts. Thus, approximately 82% of the formulated product qualifies as a minimum risk pesticide.

Additionally, citronella oil and eucalyptus oil are designated as GRAS by FDA, and cedarwood oil is listed as a food additive. The alcohols and terpenes of cedarwood oil are also considered GRAS by FDA. On p. 9 of MRID 47029303, the registrant states that an FDA listing is included as an attachment to the report. This attachment was not included in MRID 47029303.

Deficiencies: None.

VIII. PHYSICAL AND CHEMICAL CHARACTERISTICS:

- 1. <u>Methods</u>: The methods used to determine the physical/chemical characteristics are provided in Table 2.
- 2. Results: The physical/chemical characteristics of Aloe Herbal Horse Spray are provided in Table 2. A waiver for the storage stability requirement was requested based on the inability to analyze for the individual active ingredients in the product

(see enforcement analytical method section). The corrosion characteristics study is in progress.

<u>Deficiencies:</u> To address the flammability requirement, the registrant submitted "not applicable since Aloe Herbal Horse Spray does not contain any combustible liquids." The reviewer notes that the MSDSs for all the ingredients except and give a flash point. A flammability test meeting the requirements of OPPTS 830.6315 should be conducted. Results of the corrosion characteristics testing will need to be submitted upon its completion.

TAB	LE 3. Physical and Chemical Pro-	operties for Aloe Herbal Horse Sp	oray – Basie Formulation ^a
Guidel	line Reference No./Property	Description of Result	Methods
830.6302	Color	Clear, colorless @ 25°C	CCL SOP 10.12 ,
830.6303	Physical State	Liquid @ 25°C	CCL SOP 10.12
830.6304	Odor	Not required for EP	
830.6313	Stability	Not required for EP	
830.6314	Oxidation/Reduction: Chemical Incompatibility	No signs of reaction after 24 hrs exposure to powdered iron, potassium permanganate, water, or monoammonium phosphate	44 FR 16267
830.6315	Flammability	Not applicable, product does not contain any combustible liquids	
830.6316	Explodability	Not applicable, product does not contain any explosive ingredients	
830.6317	Storage Stability	Waiver requested	
830.6319	Miscibility	Not applicable, product is not to be diluted with petroleum solvents	
830.6320	Corrosion Characteristics	Study in progress	
830.6321	Dielectric Breakdown Voltage	Not applicable, product not for use around electrical equipment	
830.7000	pH	4.90 @ 25°C	CCL SOP 10.17
830.7050	UV/Visible Absorption	Not required for EP	
830.7100	Viscosity	18.266 mm ² /s (cSt) @ 22°C	ASTM Methods D 445 and D 446
830.7200	Melting Range	Not applicable, product is a liquid	
830.7220	Boiling Range	Not required for EP	
830.7300	Density/Relative Density/Bulk Density	0.8435 @ 23°C	CCL SOP 10.16
830.7370	Dissociation Constant in Water	Not required for EP	
830.7550	Partition Coefficient	Not required for EP	
830.7840	Water Solubility	Not required for EP	
830.7950	Vapor Pressure	Not required for EP	

^a Data from MRID 47029304

IX. ADDITIONAL REVIEWER=S COMMENTS: None.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100) MRID 47029305

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:		
Susan Chang, M.S.	Signature:	
-	Date:	
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature:	
	Date:	
Robert H. Ross, M.S., Group Leader	Signature:	
	Date:	
Quality Assurance:		
Eric Lewis, M.S.	Signature:	
	Date:	

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

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EPA Secondary Reviewer: Manying Xue, Chemist, 05/26/2007

STUDY TYPE: Acute Oral Toxicity - Rats (OPPTS 870.1100)

MRID NO: 47029305

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

The oral LD₅₀ for female rats was greater than 5000

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21101

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Acute Oral Toxicity Up and Down Procedure in Rats

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION:

mg/kg.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. <u>STUDY DESIGN</u>:

- I. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients
- 2. Test Animals: Three female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, and weighed 204-231 g on the day of dosing. The young adult animals, 11 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Filtered tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 19-23°C; relative humidity, 31-69%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Nos. 3101, 3102, and 3103 and were acclimated for 23 or 24 days and fasted ovemight prior to dosing. The test material (5000 mg/kg body weight) was dosed by gavage (Table 1). Body weight was recorded prior to dosing, and on days 7 and 14. The test animals were observed for mortality and clinical signs of toxicity during the first several hours post-dosing and at least daily for 14 days. All animals were necropsied.

II. RESULTS:

1. Mortality: All rats survived the study.

	TABLE 1. Doses, mo	rtality/animals treated	
Dose (mg/kg)	Males	Females	Combined
5000	-	0/3	+

Data taken from p. 10, MRID 47029305.

- 2. Body Weight: All rats gained weight during the study.
- 3. <u>Clinical Observations</u>: With the exception of one rat that had soft feces 3-4 hours post dosing, all rats appeared active and healthy throughout the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. DISCUSSION:

The oral LD₅₀ for female rats was greater than 5000 mg/kg. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is ACCEPTABLE.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (870.1200) MRID 47029306

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:		
Susan Chang, M.S.	Signature:	
	Date:	7-1-1
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature:	
	Date:	
Robert H. Ross, M.S., Group Leader	Signature:	
Nobel 11 11000 Mar. Stody Loudel	Date:	****
Quality Assurance:		
Eric Lewis, M.S.	Signature:	
	Date:	

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Ballelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Secondary Reviewer:

Manying Xue, Chemist,

05/26/2007

STUDY TYPE:

Acute Dermal Toxicity - Rats (OPPTS 870.1200)

MRID NO:

47029306

DP BARCODE NO:

DP 338682

CASE NO:

Not reported

DECISION NO:

373758

TEST MATERIAL:

Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO:

21102

SPONSOR:

Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY:

Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT:

Acute Dermal Toxicity Study in Rats - Limit Test

AUTHOR:

Jennifer Durando

STUDY COMPLETED:

December 20, 2006

GOOD LABORATORY

GLP Compliant

CONCLUSION:

PRACTICE:

The dermal LD₅₀ for males, females, and combined was

greater than 5000 mg/kg.

CLASSIFICATION:

ACCEPTABLE -- TOXICITY CATEGORY IV

I. <u>STUDY DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test Animals: Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned to groups, and weighed 247-254 g (males) and 190-206 g (females) on the day of treatment. The young adult animals, 8-9 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012 and filtered tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 20-23°C; relative humidity, 30-70%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Male Nos. 3201 to 3205; Female Nos. 3206 to 3210. The rats were acclimated for 9 days. The test material (5000 mg/kg body weight) was applied evenly over a 2 inch x 3 inch area (approximately 10% of the body surface) on the dorsal trunk and the treatment site covered with a gauze pad. The gauze pad and entire trunk were wrapped with Durapore tape. The coverings were removed after 24 hours and excess test material removed. The test animals were observed during the first several hours after treatment for mortality, signs of gross toxicity, and behavior changes and daily thereafter for 14 days. The rats were weighed prior to treatment and on days 7 and 14. The rats were euthanized on day 14 and necropsied.

II. RESULTS:

I. Mortality: All rats survived the study.

TABLE 1. Doses, mortality/animals 1reated					
Dose (mg/kg)	Males	Females	Combined		
5000	0/5	0/5	0/10		

Data taken from p. 12, MRID 47029306.

- 2. <u>Clinical Observations</u>: Erythema and edema were noted at the dose site on two males and five females on days 1, 2, 3, and/or 4. All rats appeared active and healthy throughout the study.
- 3. Body Weight: All rats gained weight during the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. <u>DISCUSSION</u>:

The acute dermal $\rm LD_{50}$ for males, females, and combined was greater than 5000 mg/kg. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE**.

ALOE HERBAL HORSE SPRAY

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300) MRID 47029307

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Signature:	
Date:	
Signature:	
Date:	·
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Signature:	
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	Date: Signature: Date: Signature: Date: Signature:

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Secondary Reviewer: Manying Xue, Chemist, 05/26/2007

STUDY TYPE: Acute Inhalation Toxicity - Rats (OPPTS 870.1300)

MRID NO: 47029307

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21103

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Acute Inhalation Toxicity Study in Rats – Limit Test

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: The inhalation LC₅₀ for males, females, and combined

was > 2.06 mg/L.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. <u>STUDY DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test Animals: Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA, were assigned to groups, and weighed 254-266 g (males) and 180-225 g (females) on the day of treatment. The young adult animals, 8-9 weeks old, were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Purina Rodent Chow No. 5012. Tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 14-22°C; relative humidity, 30-66%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Rats were ear-tagged: Male Nos. 3301 to 3305; Female Nos. 3306 to 3310. The rats were acclimated for 10 days prior to exposure. The animals were exposed to the concentration shown in Table 1. The rats were exposed nose-only in a Mini Nose-Only Inhalation Chamber (ADG Developments Ltd) for four hours and one minute. They were observed during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were sacrificed and necropsied on day 14.

Nominal	Nominal Grav.	MMAD	MMAD GSD	Particles	Тетр	Humidity	Mortality		
Conc. (mg/L)	Conc. (mg/L)	(µm)	(µm)	≤3.3 µm (%)	(°C)	(%)	Male	Female	Combine
13.08	2.06	2.4-2.6	1.87-	~83	21-22	53-57	0/5	0/5	0/10

Dala taken from Tables 4-6, pp. 9, 11, and 16-18, MRID 46523206.

Generation of the test atmosphere and description of the chamber: The exposure atmosphere was generated using a 1/4 inch JCO atomizer (Spraying Systems Inc.), FC3 fluid cap and AC1502 air cap (Robert Miller Associates). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional filtered compressed mixing air was supplied directly to the exposure chamber from a compressed air tank. The average total airflow was 25.6-25.9 liters/min and the nose-only exposure chamber volume was 6.7 L. Time to equilibrium was approximately 1 min.

<u>Test atmosphere concentration</u>: During exposure, gravimetric samples were collected from the breathing zone of the animals six times, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

<u>Particle size determination</u>: Particle size for each exposure concentration was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

II. RESULTS:

- 1. Mortality: All rats survived the study.
- 2. <u>Clinical Observations</u>: Clinical signs of toxicity were not reported for the period during exposure. Irregular respiration, hunched posture, moist rales, and/or hypoactivity were observed upon removal of the animals from the chamber. All animals had reduced fecal volume on Days I and/or 2 with recovery by Day 4 and appeared active and healthy throughout the rest of the observation period.
- 3. **Body Weight:** All rats gained weight during the study.
- 4. Gross Necropsy: No gross abnormalities were noted at necropsy.

III. DISCUSSION:

The inhalation LC₅₀ for males, females, and combined was > 2.06 mg/L. This places Aloe Herbal Horse Spray in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

ALOE HERBAL HORSE SPRAY

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870,2400) MRID 47029308

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:		
Susan Chang, M.S.	Signature:	
	Date:	
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	
Robert H. Ross, M.S., Group Leader	Signature: Date:	-
Quality Assurance:	Date.	
Eric Lewis, M.S.	Signature: Date:	

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

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EPA Secondary Reviewer: Manying Xue, Chemist, 05/26/2007

STUDY TYPE: Acute Eye Irritation - Rabbits (OPPTS 870.2400)

MRID NO: 47029308

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21104

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Primary Eye Irritation Study in Rabbits

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: Corneal opacity was noted on 1/3 rabbits at 1 and 24

hours after test material instillation with resolution by 48 hours. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48

hours and on two rabbit by 72 hours. Positive

conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation. Aloe Herbal Horse Spray was

moderately irritating.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY III

2 15

I. <u>STUDY DESIGN</u>:

- 1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. Test Animals: Three male young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Rabbit Chow No. 5326. Filtered tap water was available ad libitum. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 48-72%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: The rabbits were ear-tagged: Nos. 3401 to 3403 and were acclimated for 14 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for approximately one second. The left eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours and at 4 days after test material instillation.

II. RESULTS:

- 1. Mortality: All rabbits survived the study.
- 2. Ocular Lesions: Corneal opacity was noted on 1/3 rabbits at 1 and 24 hours after test material instillation with resolution by 24 hours (Table 1). Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbit by 72 hours (Table 2). Positive conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation (Table 3).

TABLE	1. Indivi	dual Male	e (M) and		F) Eye Sco ea of Opac	res w/ Time city)	e: Cornea	(A=Dens	ity of Op	aeity,
Animal	1 h	our	24	nours	48 h	ours	72 h	ours	4 days	
No.	A	В	A	В	A	В	A	В	A	В
3401	0	4	0	4	0	4	0	4	0	4
3402	0	4	0	4	0	4	0	4	0	4
3403	1	1	1	1	0	4	0	4	0	4

Score Conditions	I hour	24 hours	48 hours	72 hours	4 days
Conjunctiva					
Erythema	2	2	1 to 2	I	0
Chemosis	1 to 2	1	0 to 1	0	0
Discharge	2-3	1 to 2	0 to I	0	0
Iris	I	I	0 to 1	0	0

Irritation score is based on Draize Method

Cornea

Scale for Scoring Ocular Lesions

-	
A.	Opacity-degree of density (area most dense taken for reading)
	No Opacity0 Scattered or diffuse area, details of iris clearly visible!*
	Easily discernible translucent areas, details of iris slightly obscured
	Opalescent areas, no details of iris visible, size of pupil barely discernible
	Opaque, iris invisible
B.	Area of cornea involved
	One quarter (or less) but not zero
	Greater than one quarter, but less than half2
	Greater than half, but less than three quarters
	Greater than three quarters, up to whole area
	Score = A x B x 5 Total Maximum Score = 80
<u>Iris</u>	
	Values
	Normal 0
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination
	of any thereof), iris still reacting to light (sluggish reaction is positive)
	No reaction to light, hemorrhage, gross destruction (any or all of these)2*
	Score = $A \times 5$ Total Maximum Score = 10
Cor	njunctivae
A.	Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)
	Vessels normal0
	Vessels definitely injected above normal
	More diffuse, deeper crimson red, individual vessels not easily discernible2*
	Diffuse beefy red
В.	Chemosis
	No swelling0
	Any swelling above normal (includes nictitating membrane)
	Obvious swelling with partial eversion of lids2*
	Swelling with lids about half closed
	Swelling with lids about half closed to completely closed4*
C.	Discharge
	No discharge0
	Any amount different from normal (does not include small amounts observed in inner canthus of
	normal animals)
	Discharge with moistening of the lids and hairs just adjacent to lids2
	Discharge with moistening of the lids and hairs, and considerable area around the eye
	Score = $(A + B + C) \times 2$ Total Maximum Score = 20

^{*} represents a positive response

Animal #	1 hour	24 hours	48 hours	72 hours	4 days
3401	15	13	11	2	0
3402	15	13	4	2	0
3403	24	20	9	2	0
Average scores	18.0	15.3	8.0	2.0	0.0

^aFormula: Total Irritation Score = 1 + I1 + III, where,

III. DISCUSSION:

Corneal opacity was noted on 1/3 rabbits at 1 and 24 hours after test material instillation with resolution by 48 hours. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbit by 72 hours. Positive conjunctival irritation (score 2 or 3) was noted one hour after test material instillation with resolution on one rabbit by 48 hours and on the other rabbits by 72 hours. The maximum average score was 18.0 at one hour after test material instillation. Aloe Herbal Horse Spray was moderately irritating and is in TOXICITY CATEGORY III. The packet classification is ACCEPTABLE.

5

 $^{1 = \}text{Corneal Score} = [\text{Density (A) } \times \text{Area (B)}] \times 5$

II = Iris Score = Severity x 5

III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2

^bAverage Primary Irritation = Sum of Total Irritation Scores ÷ 3

DATA EVALUATION RECORD

ALOE HERBAL HORSE SPRAY

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500) MRID 47029309

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer: Manying X

Manying Xue, Chemist, 05/26/2007

STUDY TYPE:

Primary Dermal Irritation - Rabbits (OPPTS 870.2500)

MRID NO:

47029309

DP BARCODE NO:

DP 338682

CASE NO:

Not reported

DECISION NO:

373758

TEST MATERIAL:

Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO:

21105

SPONSOR:

Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY:

Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT:

Primary Skin Irritation Study in Rabbits

AUTHOR:

Jennifer Durando

STUDY COMPLETED:

December 20, 2006

GOOD LABORATORY

GLP Compliant

PRACTICE:

CONCLUSION:

Well defined moderate to severe erythema was noted on all rabbits 30-60 minutes after patch removal that persisted through day 14. Clearance on two rabbits was noted by day 14. Slight edema was noted on all animals 30-60 minutes after patch removal with clearance by Day

14. The primary irritation index was 3.8.

CLASSIFICATION:

ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. <u>Test Material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.

2. <u>Test Animals</u>: Three female young adult New Zealand White rabbits were received from Robinson Services, Inc., Clemmons, NC. The animals were housed individually in suspended stainless steel cages with mesh floors. The animals were fed Pelleted Purina Chow No. 5326. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 46-72%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.

3. Methods: The rabbits were ear-tagged, Nos. 3501to 3503, and were acclimated for 8 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. The rabbits were treated with 0.5 mL of test material applied on a 6 cm² clipped intact site, and the site covered with gauze pad. The pad and entire trunk were wrapped with a semi-occlusive Micropore tape and Elizabethan collars were placed on the rabbits. The covering and the collar were removed four hours later and the site cleansed to remove any residual test material. The animals were observed at least once daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours and at 7, 10, and 14 days after removal of the patch.

II. RESULTS:

- 1. Mortality: All rabbits survived the study.
- 2. <u>Dermal responses</u>: Well defined erythema was noted on 2/3 rabbits 30-60 minutes after patch removal that persisted through 72 hours. The erythema reduced on one rabbit by Day 7 and persisted on one rabbit through Day 14. The third rabbit had well defined erythema 30-60 minutes after patch removal, moderate to severe erythema by 24 hours, well defined erythema at 72 hours, that reduced to very slight erythema by Day 10. The primary irritation index was 3.8.

Irritation Scores:

		Hours			Days		
Animal Nos.	1	24	48	72	7	10	14
3501	2/2ª	2/2	2/1	2/I	1/1	1/1	1/0
3502	2/2	2/2	2/2	2/1	J/ 1	0/0	0/0
3503	2/2	3/2	2/2	2/1	1/1	1/0	0/0

Daia laken from Table 1, p. 13, MRID 47029309.

Description of rating method:

Evaluation of Skin Reaction:	Score
Erythema formation:	
No erythema	
Very slight erythema (barely perceptible)	1
Well-defined erylliema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema Formation:	
No edema	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderale edema (raised approximately 1 mm)	3
Severe edema (raised by more than I mm exjending beyond the area of exposure)	4

[&]quot;Erythema/Edema

III. <u>DISCUSSION</u>:

Well defined erythema was noted on 2/3 rabbits 30-60 minutes hour after patch removal that reduced to very slight erythema on one rabbit through Day 7 with clearance by Day 10 and on another rabbit through Day 14. The third rabbit had well defined erythema 30-60 minutes after patch removal, moderate to severe erythema by 24 hours, well defined erythema by 48 and 72 hours, that reduced to very slight erythema by Day 10 with clearance by Day 14. Slight edema was noted on all animals 30-60 minutes after patch removal that persisted on some animals through Day 14. The primary irritation index was 3.8. Aloe Herbal Horse Spray was moderately irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE**.

DATA EVALUATION RECORD

ALOE HERBAL HORSE SPRAY

STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG (870.2600) MRID 47029310

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 07-033

Primary Reviewer:		
Susan Chang, M.S.	Signature:	
	Date:	
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature:	
	Date:	
Robert H. Ross, M.S., Group Leader	Signature:	
	Date:	
Quality Assurance:		
Eric Lewis, M.S.	Signature:	<u>,</u>
	Date:	

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer: Manying Xue, Čhemist, 05/26/2007

STUDY TYPE: Skin Sensitization - Guinea Pigs (OPPTS 870.2600)

MRID NO: 47029310

DP BARCODE NO: DP 338682

CASE NO: Not reported

DECISION NO: 373758

TEST MATERIAL: Aloe Herbal Horse Spray (EPA Reg. No. 66963-I, 0.75%

Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus

Oil Eucalyptus Globulus, active ingredients)

PROJECT NO: 21106

SPONSOR: Espree Animal Products, Inc., Grapevine, TX

TESTING FACILITY: Eurofins/Product Safety Laboratories, Dayton, NJ

TITLE OF REPORT: Dermal Sensitization Study in Guinea Pigs (Buehler

Method)

AUTHOR: Jennifer Durando

STUDY COMPLETED: December 20, 2006

GOOD LABORATORY GLP Compliant

PRACTICE:

CONCLUSION: After three consecutive weekly inductions, the test

animals showed positive signs of irritation 24 and 48 hours after challenge. Aloe Herbal Horse Spray was a

dermal sensitizer.

CLASSIFICATION: ACCEPTABLE

I. <u>STUDY DESIGN</u>:

- 1. <u>Test material</u>: Aloe Herbal Horse Spray containing 0.75% Citronella Oil, 0.50% Cedar Oil, and 0.378% Eucalyptus Oil Eucalyptus Globulus as active ingredients.
- 2. <u>Test animals</u>: Thirty female Hartley guinea pigs were received from Elm Hill Breeding Labs, Chelmsford, MA, were assigned to groups, and weighed 318-403 g at experiment start. The body weight was not reported for four males that were used for preliminary irritation testing. The young adult animals were housed individually in suspended stainless steel cages with mesh or plastic perforated floors. The animals were fed pelleted Purina Guinea Pig Chow No. 5025. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-22°C; relative humidity, 48-75%; and photoperiod, 12 hour light/dark cycle. Air changes per hour were not reported.
- 3. Methods: Male and Female guinea pigs were marked with color codes and grouped: Preliminary irritation testing Nos. 3680 to 3683 (males); Test Nos. 3601 to 3620 (females); Naive Control Nos. 3621 to 3630 (females). The guinea pigs were acclimated for 7-39 days. The animals were induced and challenged according to the method of Buehler. From the results of the preliminary irritation testing, undiluted test material was used for induction and challenge. The dorsal and flank areas of 20 test guinea pigs and 10 naive control animals were clipped prior to each treatment. For the induction, 0.4 mL undiluted test material was applied to the animal using a Hill Top Chamber secured with non-allergenic adhesive tape. The chamber and excess test material were removed after six hours. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.4 mL of undiluted test material. Reactions were scored at approximately 24 and 48 hours following induction and challenge application.

II. RESULTS:

- 1. Mortality: All animals survived the study.
- 2. Body Weight: All animals gained weight during the study.
- 3. Skin Effects: Very faint usually non-confluent erythema was noted on 8/20 test animals 24 hours after the first induction with clearance on 4/12 animals by 48 hours. Very faint usually non-confluent erythema was noted on 12/20 test animals 24 hours after the second induction that persisted through 48 hours. Very faint usually non-confluent erythema and faint usually confluent erythema were noted on 11/20 and 8/20 test animals, respectively, 24 hours after the third induction and on 15/20 and 3/20 test animals, respectively, 48 hours after the third induction. Faint usually confluent erythema was noted on 11/20 test animals 24 hours after challenge and on 9/20 test animals 48 hours after challenge. Very faint usually non-confluent erythema was noted on 6/10 naive control animals 24 hours after challenge with clearance on four animals by 48 hours.

TABL	E 1. Summary of	Individual	Erythema	Challenge	Scores wit	h Time *		
		24 h	ours		48 hours			
Erythema Score	0	0.5	1.0	2.0	0	0.5	1.0	2.0
Treated	1	8	11	0	3	8	- 9	0
Naive Control	4	6	0	0	8	2	0	0

aNumber of animals affected

Evaluation score is based on Buehler Grading Scale.

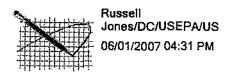
Scale for Scoring Skin Reaction

Buehler sensitization scoring scale

<u>Grythema</u>	Seore
No reaction	
/ery faint, usually nonconfluent	0.5
aint, usually confluent	
Anderate	
severe with or without edema	3

III. <u>DISCUSSION</u>:

After three consecutive weekly inductions, the test animals showed positive signs of reactivity while the naive control animals showed no positive signs of reactivity 24 and 48 hours after challenge. The study included an alpha-hexylcinnamaldehyde (HCA) positive control study which was carried out within six months of the study and the results were appropriate. Aloe Herbal Horse Spray was a dermal sensitizer. The packet is classified as **ACCEPTABLE**.



To Todd Peterson/DC/USEPA/US@EPA

cc Manying Xue/DC/USEPA/US@EPA

bcc

Subject Re: Question about Review for 66963-i Aloe Herbai Horse Spray P

History:

This message has been replied to.

Todd:

Manying and I discussed the efficacy issue and we were a little uncertain regarding the need for any efficacy data since the pests targeted are considered public health pests, but the animal being protected is a horse, not a human. We ultimately decided that maybe the risk manager (you) might make the final call. I'm not sure that we really need any efficacy data.

Russ

Russell S. Jones, Ph.D., Senior Biologist Chair, Biochemical Classification Committee Biochemicals Branch Science Team Captain Biopesticides & Pollution Prevention Division (75 t1P) Office of Pesticide Programs U.S. Environmental Protection Agency 2227 South Crystal Drive One Potomac Yard, 8th Floor Arlington, VA 22202 Ph: 703/308-5071 FAX: 703/308-7026

jones.russell@epa.gov

Visit http://www.epa.gov/pesticides

----Todd Peterson/DC/USEPA/US wrote: ----

To: Manying Xue/DC/USEPA/US@EPA From: Todd Peterson/DC/USEPA/US Date: 06/01/2007 03:55PM

cc: Russell Jones/DC/USEPA/US@EPA

Subject: Question about Review for 66963-I Aloe Herbal Horse Spray

Hi Manying,

I wanted to know if you may still have any other papers from the review for the data for this product? I think there were some things I expect to get back with the review memo. Let me know if you have a copy of the transmittal letter, a label, or anything else that goes with this application.

Also, the review states that the registrant needs to submit product performance data This statement is not clear to me.

Do you mean performance to demonstrate how often the product is to be applied? Or, are you saying we need to demonstrate that the product actually repels the stated pests? Or, do we need both types of data?

To just say performance data are needed without being just a little more specific leaves me to wonder what to ask for!

Also, why do we need this data? If it is to support a label claim, then I understand. If this is in relation to human health pests, then do we need this for use on a horse?

I apologize if I'm missing something simple. I have called up the jacket and will get some more information to help me once that is available.

It appears that aside from the product performance data, we can register the product with changes to the CSF and possibly conditions that they supply other data in the near future.

Best Regards,

Todd Peterson, Ph.D, Biologist USEPA, OPP, Biopesticides and Pollution Prevention Division 703-308-7224

LEWIS & HARRISON

122 C Streef, N.W., Suite 740 Washington, D.C. 20001

telephone 202,393,3903 1ax 202,393,3906

Consultants in Government Affairs

January 4, 2007

HAND DELIVERED

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

To:	Todd Peterson, Ph.D. (7511P) Biopesticides and Pollution Prevention Division (BPPD)	200	୍ଟ ଓଡ଼ ପ୍ରସ୍ଥରୀ ସଂଖ୍ୟା
RE:	Registration Application for a New End-Use Product Product: Aloe Herbal Horse Spray EPA File Symbol: 66963-	. •	多 数 (3 4 表 4 元 元 (3 7 元 元 元 元 元 元 元 元 元 元 元 元 元 元 元 元 元 元
	Registrant: Espree Animal Products, Inc. PRIA Category B72, New Product, Me-Too, Non-Fast Track PRIA Fee is \$0 (100% Fee Waiver Request)		р Модел В Фодел Межен — — — — — — — — — — — — — — — — — — —

Dear Dr. Peterson:

On behalf of Rhodia Inc., I am submitting a registration application for Aloe Herbal Horse Spray, a new-use product. As mentioned at our September 2006 pre-submission meeting, this product contains three active ingredients: citronella oil, cedarwood oil, and eucalyptus oil.

PRODUCT CHEMISTRY DATA

Aloe Herbal Horse Spray uses three unregistered actives to formulate this product. As mentioned at the pre-submission meeting, we are supplying certificates of analysis on these source materials (please refer to Volume 1).

The three actives in this product are all essential oils. Since none of these materials is a discrete chemical, product analysis for each active (when used in combination) cannot be performed. Thus, we are requesting a waiver for the enforcement analytical method and the one-year storage stability. This waiver request is attached as Volume 3.

TOXICOLOGY

Espree is submitting product-specific acute toxicology studies to support this registration. These are being submitted as Volumes 5-10.

LABELING

Espree is current labeling is for an indoor, non-food use product.

EFFICACY

No public health claims are being proposed for this product; therefore no efficacy is required.

In support of this application, please find enclosed the following documents:

- 1) Small Business Waiver Request
- 2) Application for Pesticide Registration form.
- 3) One (1) copy of the Confidential Statement of Formula (CSF) form for both a basic and alternative formulation.
- 4) Five (5) copies of the proposed product label.
- 5) Certification with Respect to Data Compensation form.
- 6) Data Matrix Chart for each of the active ingredients.
- 7) Product-Specific Data Matrix Chart.
- 8) Three (3) copies of the Summary of the Physical/Chemical Properties worksheet .:.
- 9) Three (3) copies of the Product Chemistry and Acute Toxicology data volumes. .

Lewis & Harrison is acting on behalf of Espree as both the "Company Agent" and "Contact Point". Accordingly, please relay all questions and correspondence, including notification of the MRID numbers and Data Evaluation Records, directly to us.

If you have any questions about this submission, please contact either Eliot Harrison at (202) 393-3903 ext. 14 or me at (202) 393-3903 ext. 13.

Sincerely,

Catherine Rice

Agent for Espree Animal Products, Inc.



122 C Street, N.W., Suite 740 Washington, D.C. 20001

telephone 202,393,3903 fax 202,393,3906

January 4, 2007

HAND DELIVERED

Document Processing Desk (APPL) Office of Pesticide Programs (7504P) US Environmental Protection Agency One Potomac Yard 2777 S Crystal Drive Arlington, VA 22202

To: Todd Peterson, Ph.D. (7511P)

Biopesticides and Pollution Prevention Division (BPPD)

RE: Registration Application for a New End-Use Product

Product: Aloe Herbal Horse Spray

EPA File Symbol: 66963-

Registrant: Espree Animal Products, Inc.

Data Transmittal Letter for Studies Supporting the Registration Application

of Aloe Herbal Horse Spray

Dear Dr. Peterson:

On behalf of Espree Animal Products, Inc., I am submitting three (3) copies of the following studies in support of the Section 3 registration application for Aloe Herbal Horse Spray:

- Volume 1 of 10 Aloe Herbal Horse Spray: Product Identity and Composition Source Active Ingredients. January 3, 2007. 31 pp. MRID#
- Volume 2 of 10 Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. January 3, 2007. 4 pp. and 46 conf. pp. MRID#

- Volume 3 of 10
 Aloe Herbal Horse Spray: Wavier Request for Enforcement Analytical Method and Storage Stability. January 3, 2007. 9 pp.

 MRID#
- Volume 4 of 10
 Physical and chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity, and Relative Density. November 28, 2006.

 Performing Laboratory: Case Consulting Laboratories, Inc. 7 pp. MRID#
- Volume 5 of 10
 Acute Oral Toxicity Up and Down Procedure in Rats. December 20, 2006
 Performing Laboratory: Eurofins/Product Safety Laboratory. 14 pp....
 MRID #:
- Volume 6 of 10
 Acute Dermal Toxicity Study in Rats Limit Test. December 20, 2006
 Performing Laboratory: Eurofins/Product Safety Laboratory. 14 pp.
 MRID #:
- Volume 7 of 10
 Acute Inhalation Toxicity Study in Rats Limit Test. December 20, 2006
 Performing Laboratory: Eurofins/Product Safety Laboratory. 22 pp.
 MRID #:
- Volume 8 of 10
 Primary Eye Irritation Study in Rabbits. December 20, 2006

 Performing Laboratory: Eurofins/Product Safety Laboratory. 17 pp. MRID #:
- Volume 9 of 10
 Primary Skin Irritation Study in Rabbit. December 20, 2006

 Performing Laboratory: Eurofins/Product Safety Laboratory. 15 pp. MRID #:

Volume 10 of 10
 Dermal Sensitization Study in Guinea Pigs (Buehler Method). December 20, 2006

 Performing Laboratory: Eurofins/Product Safety Laboratory. 23 pp. MRID #:

If you have any questions about this submission, please contact either Eliot Harrison at (202) 393-3903 ext. 14 or me at (202) 393-3903 ext. 13.

Singerely,

Catherine Rice

Agent for Espree Animal Products, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and I hour per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)), U. S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to his address.

SUMMA	RY OF THE PHYSI	CAL/CHEMICA	L PROPERTIES (PR N	otice 98-1)		
1. PRODUCT NAME: ·			····	2. Rcg. No.		
Aloe Herbal	Horse Spray			66963- (not yet assigned		
3. COMPANY NAME:	**************************************		**************************************	4. SUBMISSION DATE:		
Espree Animal	Products, Inc.			January 4, 2007		
5. FIRST SUBMISSION [X[6. RESUBMISSION []	7. PESTICIDE TY	PE: Antimicrobia	i	10. REGISTRATION [X]		
8. FORMULATED MANUFAC	TURING-USE PRODUC	CT or 9. END-U	SE PRODUCT X [II. REREGISTRATION [
13. PRODUCT MANAGER OR Marshall Swindell, AD		MANAGER#/NAM	E (IF KNOWN):	12. REREG CASE #		
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	16. MRID or REPORT NO.					
Grou	p B, Series 830-Phys	sical and Chemica	l Properties (40CFR 15	8.190)		
-6302 Color	-6302 Color Clear, colorless					
- 6303 Physical State	Liquid					
- 6304 Odor	Not Required - per	Not Required - per PR Notice 95-2				
- 6314 Oxidation/Reduction Chemical Incompatibility	Exposure System Powdered Iron	Upon Mixing No signs of reaction	After 24 hours exposure No signs of reaction	Not yel assigned		
	Potassium permanganate	No signs of reaction	No signs of reaction			
	Water	No signs of reaction	No signs of reaction			
	Monoammonium phospate	No signs of reaction	No signs of reaction			
- 6315 Flammability/Flame Extension	Not Applicable sind combustible liquids		Spray does not contain any			
-6316 Explodability	Not Applicable sine explosive ingredien	Not Applicable since Aloe Herbal Horse Spray does not contain any				
- 6317 Storage Stability	Waiver requested t	Waiver requested under 40 CFR 158.155(f). Please refer to Volume				
- 6319 Miscibility	1	Not Applicable since Aloe Herbal horse Spray is not to be diluted with petroleum solvents.				
- 6320 Corrosion Characteristics		This study is currently being conducted. Will be submitted on				
- 6321 Dieleetrie Breakdown Voltage	Not Applicable sind electrical utilities	cc Aloe Herial Horse	Spray is not for use around			
-7000 pH	4.90 (25C)	**************************************		Not yet assigned		
- 7111 Vicosity	18.266 mm ² /s (eSt)	(22C)		Not yet assigned		
- 7300 Density/Relative Density/ Bulk Density	0.8435	-		Not yet assigned		

EPA Form 8570-36 (07/JAN/1998)



Form Approved OMB No. 2070-0060

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DATA MATRIX FOR End-Use Product Date January 4, 2007 EPA Reg. No./File Symbol 66963-Page t of 2 Applicant's/Registrant's Name & Address: Product Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051 Aloe Herbal Horse Spray Ingredient(s): Citronella Oil (PC code 021901), Cedarwood Oil (PC code 40505), Eucalyptus Oil (PC code 40503) detine Reference Number Guideline Study Name MRID Number Submitter Status Note 830,1550 Espree Animal Products (66963) OWN Footnote 1, Volume 1 Product Identity and Composition Not Yet Assigned Volume 2 Espree Animal Products (66963) 830.1600 Description of the Materials Used to Produce Not Yet Assigned Espree Animal Products (66963) OWN Volume 2 the Product 830.1650 Description of the Manufacturing Process Not Yet Assigned Espree Animal Products (66963) OWN Volume 2 Discussion of Formation of Impurities Espree Animal Products (66963) Volume 2 830.1670 Not Yet Assigned OWN Volume 2 830.1700 Preliminary Analysis Not Yet Assigned Espree Animal Products (66963) OWN 830,1750 Certified Limits Not Yet Assigned Espree Animal Products (66963) OWN Volume 2 Footnote 2, Volume 3 830,1800 Enforcement Analytical Method Waiver Requested Espree Animal Products (66963) OWN Physical/Chemical **Properties** OWN 830,6302 Volume 4 Color Not Yet Assigned Espree Animal Products (66963) Physical State Espree Animal Products (66963) OWN Volume 4 830,6303 Not Yet Assigned 830,6304 Odor Not Required Footnote 3 830.6314 Oxidation/Reduction Chemical Incompatability Not Yet Assigned Espree Animal Products (66963) OWN Volume 4 Footnote 4 830.6315 Flammability Not Required **Explodability** Not Required Footnote 4 830.6316 Footnote 2, Volume 3 830.6317 Storage stability Waiver Requested Espree Animal Products (66963) OWN Footnote 4 830.6319 Miscibility Not Required 830.6320 Corrosion characteristics Pending Footnote 5 Not Required Footnote 4 830.6321 Dielectric breakdown voltage Volume 4 830,7000 Not Yet Assigned Espree Animal Products (66963) OWN οН 830.7100 Espree Animal Products (66963) OWN Volume 4 Viscosity Not Yet Assigned 830.7300 Density/Relative Density Not Yel Assigned Espree Animal Products (66963) OWN Volume 4 TOXICCLOGY Not Yet Assigned Espree Animal Products (66963) OWN Volume 5 870.1100 **Acute Oral Toxicity** Espree Animal Products (66963) OWN Volume 6 870,1200 Acute Dermal Toxicity Not Yet Assigned 670.130C Acute Inhalation Toxicity Not Yet Assigned Espree Animal Products (66963) OWN Volume 7 670.2400 Espree Animal Products (66963) OWN Volume 8 Eximary Eye Irritation Not Yet Assigned 870.2500 OWN Volume 9 Not Yet Assigned Espree Animal Products (66963) Primary Dermal Irritation Signature

Name and Title: Catherine Rice

Agent for Espree Animal Products, Inc.

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Date

1-4:01



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DO NOT SEND THE TOTAL OLDER SOUL		ATRIX FOR End	-Use Product	·		
Date January 4, 2007					Page 1 of 2	
Applicant's/Registrant's Name	& Address:		EPA Reg. No./File Symbol %6963- Page 1 of 2 Product			
	spree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051					
			Aloe Herbat Horse Spray			
Ingredient(s): Citronetta Oit (I	PC code 021901), Cedarwood Oil (PC code 405	05), Eucalyptus Oil	(PC code 40503)			
deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	Product Identity and Composition					
830.1600	Description of the Materials Used to Produce the Product					
830.1 6 50	Description of the Manufacturing Process					
830.1670	Discussion of Formation of Impurities			······································		
830.1700	Preliminary Analysis					
830.1750	Certified Limits					
830.1800	Enforcement Analytical Method					
Physical/Chemical						
Properties					<u> </u>	
830,6302	Color					
830.6303	Physical State					
830.6304	Odor					
830.6314	Oxidation/Reduction Chemical Incompatability					
830.6315	Flammability					
830,6316	Explodability			-		
830.6317	Storage stability					
830.6319	Miscibility					
830.6320	Corrosion characteristics					
830.6321	Dielectric breakdown voltage					
830.7000	pH					
830.7100	Viscosity					
830.7300	Density/Relative Density					
				7111111111		
870.1100	Acute Oral Toxicity					
870.12 0 0	Acute Dermal Toxicity					
870.1300	Acute Inhalation Toxicity					
870.2400	Primary Eye Irritation		1			
870.2500	Primary Dermal Irritation					
		· · · · · · · · · · · · · · · · · · ·	1	\		
Signature / /o	<u> </u>		Name and Title: Catherine Rice		Date 13	

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Name and Title: Catherine Rice Agent for Espree Animal Products, Inc.

Date / -4·07



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DATA MATRIX FOR End-Use Product						
Date January 4, 2007	,		EPA Reg. No./File Symbol 66963-	•	Page 2 of 2	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
Ingredient(s): Citronella Oil (l	^o C code 021901), Cedarwood Oil (PC	code 40505), Eucalyptus Oil (F	C code 40503)			
*deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
870.2600	Skin Sensitization	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 10	
EFFICAC'	Y					
96-9	Product Performance	-		-	Not required, no human health claims.	

FOOTNOTES

- Information on the three source active ingredients is submitted as Volume 1.
- Waiver requested for the enforcement analytical method and storage stability since this product contains three essential oils in combination. The rationale for this waiver request is presented as Volume 2.
- 3 Per PR Notice 95-2, these studies are not required.
- These data requirements are not required, as described on the attached "Summary of Physical-Chemical Properties" worksheet.
- 5 The one-year corrosion characteristics study is ongoing. The study will be submitted upon completion.

	Name and Title: Catherine Rice	Date
1 autur- 1.	Agent for Espree Animal Products, Inc.	1-4-07



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		DATA MATRIX FOR End	-Use Product	1 4 g 0 ,		
Date January 4, 2007	January 4, 2007			€ <mark>€963</mark> -	Page 2 of 2	
Applicant's/Registrant's Name a Espree Animal Products, In	& Address: c. PO Box 3650, Grapevine, TX 760	51	Product Aloe Herbal Horse Spray	•		
Ingredient(s): Citronella Oil (F	PC code 021901), Cedarwood Oil (PC	code 40505), Eucalyptus Oil	(PC code 40503)			
eline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
870.2600	Skin Sensitization					
EFFICAC)	EFFICACY					
96-9	Product Performance					

FOOTNOTES



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Signature Agent for Espree Animal Products, Inc.

| Name and Title: Catherine Rice Agent for Espree Animal Products, Inc. | 1-4-07



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	. DATA M	ATRIX FOR ACTIV	E INGREDIENT	। ' प्रे प क किंच	
Date January 4, 2007			EPA Reg. No./File Symb	Page t of 3	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spi	ray		
Ingredient(s): Oil of citronella	(PC code 021901)				
deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151B-10 – 151B-15	Product Identity, Composition, and Analysis				
151B-17	Physical/Chemical Properties				
TOXICOL					
152B-10	Acute Oral Toxicity				
152B-11	Acute Dermal Toxicity				
152B-12	Acute Inhalation Toxicity				-
152B-13	Primary Eye Irritation				
152B-14	Primary Dermal Irritation				
152B-15	Dermal Sensitization				
152B-16	Hypersensitivity				
152B-17	Microbial mutagenicity				
152B-18	Immunotoxicity				
152B-20	90-Day oral toxicity				
152B-21	90-Day dermal toxicity	***************************************			,
152B-23	Developmental Toxicity				
ECOL O GI	CAL EFFECTS				
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Name and Title: Catherine Rice, Agent for Espree Animal products, Inc.

Date /-94 ())



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	. DATA	MATRIX FOR ACTIV	/E INGREDIENT	ልድርክ መ ሕዝመ .	
Date January 4, 2007			EPA Reg. No./File Symbo	រុំ ្នូ6,65,63~	Page 2 of 3
Applicant's/Registrant's Name & Address: Espree Animat Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray			
tenredient(s): Oit of citronella	(PC code 021901)				
್ಪ್ರ.deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154B-6	Acute Avian Oral				
154B-7	Avian Subacute Dietary Toxicity				
15 4 B-8	Fish toxicity				
15 4B -9	Invertebrate Toxicily				
154B-10	Nontarget plants				
154B-11	Nonlarget insects				
ENVIRON	MENTAL FATE				
	ALL				

FOOTNOTES



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Signature Athle 1

Name and Title: Catherine Rice, Agent for Espree Animal products, Inc.

Date /-4-07



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,′ D.	ATA MATRIX FOR ACTIV	E INGREDIEN I	பிருந்த சி மே நேரோல் ந	
Date January 4, 2007		EPA Reg. No./File Symb	စ်(၂ 66 363-	Page 3 of 3
Appticant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray		
Ingredient(s): Oil of citronella (PC code 021901)				9 3. 8.4.4
ideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note



Signature

Name and Title: Catherine Rice,
Agent for Espree Animal products, Inc.

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Date 1-4.07



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	DATA N	ATRIX FOR ACTIVE	INGREDIENT		
Date January 4, 2007			EPA Reg. No./File Symbol; *66963-		
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray			
Ingredient(s): Oil of citronella	(PC code 021901)				
[↑] deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151B-10 - 151B-15	Product Identity, Composition, and Analysis	41785703	Candle Corp (009201)	OLD	(t)
151B-17	Physical/Chemical Properties	41785703	Candle Corp (009201)	OLD	(t)
TOXICOL					
152B-10	Acute Oral Toxicity	41747402 43179401	Candle Corp (009201) Citronella Joint Venture (6773	OLD (6) PAY	(1) (3)
152B-11	Acute Dermal Toxicity	41747403 43167101	Candle Corp (009201) Citronella Joint Venture (6773	OLD	(1)
152B-12	Acute Inhalation Toxicity	41747404 43167102	Candle Corp (009201) Citronella Joint Venture (6773	OFD	(t) (3)
152B-13	Primary Eye Irritation	41747405 43167103	Candle Corp (009201) Citronella Joint Venture (6773	OLD	(1) (3)
152B-14	Primary Dermal Irritation	41747406 43167104	Candle Corp (009201) Citronella Joint Venture (6773	OLD	(t) (3)
152B-15	Dermal Sensitization	41747407 43167105	Candle Corp (009201) Citronella Joint Venture (6773	OLD	(1) (3)
152B-16	Hypersensitivity				Not Applicable
152B-17	Microbial mutagenicity	41786701 41785702 41747408	Citronella Joint Venture (6773 Citronella Joint Venture (6773 Candle Corp (009201)		(1)
152B-18	Immunotoxicity	-			Waiver Request (2)
152B-20	90-Day oral toxicity	-		-	Waiver Request (2)
152B-21	90-Day dermal toxicity	-		-	Waiver Request (2)
152B-23	Developmental Toxicity	-		-	Waiver Request (2
ECOLOG	ICAL EFFECTS				

	Name of Title Oak deep Dise	Data
Signature / i / A	Name and Title: Catherine Rice,	Date
1 (14-61; a = 11);	Agent for Espree Animal products, Inc.	1-4-0-
<u>COCOMO C</u>		



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	DATA	MATRIX FOR ACTIVE	INGREDIENT	•	
Date January 4, 2007		<u></u>	EPA Reg. No./File Symbol 669	33-	Page 2 of 3
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray			
Ingredient(s): Oil of citronella	(PC code 021901)				
Prideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154B-6	Acute Avian Oral	41747409	Candle Corp (009201)	OLD	(1)
154B-7	Avian Subacute Dietary Toxicity	-		-	Waiver Request (2
154B-8	Fish toxicity	41747410	Candle Corp (009201)	OLD	It)
154B-9	Invertebrate Toxicity	41747411	Candle Corp (009201)	. OLD	(t)
154B-10	Nontarget plants	+			Waiver Request (2
154B-11	Nontarget insects	4		<u> </u>	Waiver Request (2
ENVIRON	MENTAL FATE				
	TALL	*		<u> </u>	Waiver Request (2

FOOTNOTES

- 1. Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been fulfilled.
- 2. Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been waived.
- 3. The Data Submitters List (9/30/2006) does not list this company (67736) as a data submitter for oil of citronella. As a result, no offer to pay letter has been sent.

entronella (CAS Reg. No. 8000-29-1, OPP chemical code 02 t901) is covered by the Oil of Citronella RED. Page 2-3 pf the RED address the use profile:

Type of Pesticides - biochemical - insect and animal repellent

Use Sites:

Indoor nonfood: Animal treatment - horse-show/race/special, ponies

Indoor residential: human body/clothing while being worn (insect control); skin contact treatment, animal treatment (flea collar)

Outdoor residential: household/domestic dwelling outdoor premise use

Terrestrial non-food + outdoor residential; ornamental and/or share trees; ornamental herbaceous plants; ornamental woody shrubs and vines

Target Pests:

biting midges, biting flies, black flies, bugs, cats, deer flies, deer ticks, dogs, face flies, flying insects, gnats, horn flies, horse flies, house flies, insects, mosquitoes, "no-see-ums", stable flies

Formulation Types registered:

Signature // /	Name and Title: Catherine Rice,	Date
(lithing / !	Agent for Espree Animal products, Inc.	1-4-07
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	, D A	TA MATRIX FOR ACTIV		Creation and Company		
Date January 4, 2007	,		EPA Reg. No./File Symbol	r66963-	Page 3 of 3	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Association Aloe Herbal Horse Spray			
Ingredient(s): Oil of citronella (PC code 021901)						
1 Teline Reference Number Guideline Study Na	me	MRID Number	Submitter	Status	Note	

Liquid ready to use, impregnates material, pelleted/tableted, impregnated collar/tag

Method and Rates of Application

Types of treatment: hand held sprayer, cloth wipe-on, candle, cartridge, rub-on, scent post application, sprinkle by hand, flea collar

Method and Rate: varies

Timing: as needed

Use Practice Limitations: None

The proposed product will be used a fly repeilent to be used on horses. The percent of citronella oil will be 0.75%.

Rationate for Waiver Request: The use patterns addressed in the RED is includes a use that is almost identical the proposed use pattern (horses); however, this is for indoor uses and the proposed product also includes outdoor uses. Please note that the RED does include some outdoor residential uses. Based on this, we believe that the RED adequately covers this use pattern. Thus, according to the RED, the generic product chemistry, ecological effects, toxicology, and environmental fate data requirements have either been satisfied and/or waiver.



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Signature / . Name and Title: Catherine Rice, Agent for Espree Animal products, Inc. Date 1-4-07

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Oo not send the torm to this address		TRIX FOR ACTIV	E INC	REDIENT :		
Date January 4, 2007	(Page 1 of 2
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
Ingredient(s): Cedarwood oil	(PC code 40505)					· · · · · · · · · · · · · · · · · · ·
deline Reference Number				bmitter	Status	Note
61- 62-	Product Identity, Composition, and Analysis					
63-	Physical/Chemical Properties					
TOXICOL		······································			<u></u>	
81-1	Acute Oral Toxicity					-
81-2	Acute Dermal Toxicity					
81-3	Acute Inhalation Toxicity					
81-4	Primary Eye Irritation					
81-5	Primary Dermal Irritation					
81-6	Skin Sensitization					
84-2A	Gene Mutation (Ames Test)		·····			
84-2B	Structural Chromosomal Aberration					
84- 4	Other Genotoxic Effects					
ECOLOGI	CAL EFFECTS		****			
71-1A	Acute Avian Oral - Quail/Duck			1		
71-2B	Avian Dietary - Quail		· · · · · · · · · · · · · · · · · · ·		·······	
72-1A	Fish toxicity - Bluegill					
72-1C	Fish Toxicity - Rainbow Trout					
72-2A	Invertebrate Toxicity					
	MENTAL FATE					
© 835.2120/161-1	Hydrolysis					

Signature (ithura- N.	Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc.	Date 1-4-07
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	, DA	TA MATRIX FOR ACTIV	E INGREDIENT	9	
Date January 4, 2007	,		EPA Reg. No./File Symbo	ol 66963-	Page 2 of 2
Applicant's/Registrant's Name Espree Animal Products, In	& Address: ec. PO Box 3650, Grapevine, TX 7605	51	Product Aloe Herbal Horse Spr	ay	
Ingredient(s): Cedarwood oil	(PC code 40505)		***************************************		
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

FOOTNOTES



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Signature (Uthura-A

Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc.

Date /-4-07



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DATA MATRIX FOR ACTIVE INGREDIENT EPA Reg. No./File Symbol . 36903-Date January 4, 2007 Page t of 2 Applicant's/Registrant's Name & Address: Product Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051 Aloe Herbal Horse Spray Ingredient(s): Cedarwood oil (PC code 40505) 'deline Reference Number Guideline Study Name MRID Number Submitter Status Note 61-Product Identity, Composition, and (1)62-Analysis 42319001 PAY (3)Whitney Corr-Pak (65813) 42101201 Arbor American (65555) OLD 41549503 Boswell R&D (63380) OLD 42362601 P&M Consumer (66099) PAY (4)42362602 P&M Consumer (66099) PAY (4)(3)42319002 Whitney Corr-Pak (65813) PAY 63-Physical/Chemical Properties SATISIFIED (1) TOXICOLOGY Waiver Request (2) 81-1 Acute Oral Toxicity Waiver Request (2) 81-2 Acute Dermal Toxicity Waiver Request (2) 81-3 Acute Inhalation Toxicity Waiver Request (2) 81-4 Primary Eye Irritation 81-5 Primary Dermal Irritation Waiver Request (2) 81-6 Skin Sensitization Waiver Request (2) Waiver Request 84-2A Gene Mutation (Ames Test) Waiver Request (2) 84-2B Structural Chromosomal Aberration Waiver Request (2) 84-4 Other Genotoxic Effects

 71-2B
 Avian Dietary – Quail
 Waiver Request (2)

 72-1A
 Fish toxicity - Bluegill
 Waiver Request (2)

 72-1C
 Fish Toxicity - Rainbow Trout
 Waiver Request (2)

 72-2A
 Invertebrate Toxicity
 Waiver Request (2)

 ENVIRONMENTAL FATE

 ™835.2120/161-1
 Hydrolysis
 Waiver Request (2)

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Signature /	/]	•
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/	11.1-16	1 1 11 11
	- L X	

71-1A

Name and Title: Catherine Rice,
Agent for Espree Animals Products, Inc.

Waiver Request (2)

ECOLOGICAL EFFECTS

Acute Avian Oral - Quail/Duck



Form Approved OMB No. 2070-0060

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	_ 0	ATA MATRIX FOR ACTIV	'E INGREDIENT	***	
Date January 4, 2007	,		EPA Reg. No./Fil	e Symbol - •66933-	Page 2 of 2
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product	¢ ∳∝: .	
			Aloe Herbal Ho	rse Spray	
Ingredient(s): Cedarwood oil	(PC code 40505)				
Crideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note

⊢ JOTNOTES

- Per page 20 of the Cedarwood Oil RED, the product chemistry generic data requirements have been satisfied.
- Per pages 21-22 of the Cedarwood Oil RED, the ecological effects, toxicology, and environmental fate generic data can be waived.
- The Data Submitters List (9/30/2006) does not list this company (65813) as a data submitter for cedarwood oil. As a result, no offer to pay letter
 has been sent.
- The Data Submitters List (9/30/2006) does not list this company (66099) as a data submitter for cedarwood oil. As a result, no offer to pay letter
 has been sent.

Cedarwood oil (CAS Reg. No. 800-27-9, OPP chemical code 40505) is covered by the September 1993 Cedarwood Oil RED.

Pages 2-3 of the RED address the use profile:

Type of Pesticides: repellent/feeding depressant; fungicide

Use sites: indoor residential: domestic dwellings and their contents, pets/animals (presumable cats and dogs) and their living and sleeping quarters

Target pets: fleas, moths, mildew

Formulation types registered:

Ready to use spray – sprayed on animal bedding (0.48%)

Impregnated pet collar tag (0.5%)

Wood blocks (2-8%)

The proposed product will be used a fly repellent to be used on horses. The percent of Cedarwood oil will be 0.50%.

Rationale for Waiver Request: The use patterns addressed in the RED are slightly different from the proposed product's use pattern. However, both will be used on non-humans (pets vs. horses) to repel nuisance insects (fleas and moths vs. flies). Additionally, the lowest rate covered by the RED is ready to use sprays at 0.48%. In the concentrated form, Aloe Herbal Horse Spray contains 0.50% cedarwood oil. According to the product's use directions, this concentrate is then to be diluted with a minimum of 4 parts water. Thus, the end use will contain 0.129% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic product chemistry data requirements have been satisfied and the ecological effects, toxicology, and environmental fate data requirements can be waived.

Signature / i d	Name and Title: Catherine Rice,	Date !
		1 1 / 1 1
I = I I + I I I I I I I I I I I I I I I	Agent for Espree Animals Products, Inc.	1 1-4-[] 1
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✓ DATA M	ATRIX FOR ACTIV	E INGKEDIEN I	5. s			
,	EPA Reg. No./File Symbol	6696Ö-	Page t of 2			
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
PC code 40503)						
Guideline Study Name	MRID Number	Submitter	Status	Note		
Product Identity, Composition, and Analysis						
	<u></u>					
Primary Dermal Irritation						
Gene Mutation (Ames Test)						
Structural Chromosomal Aberration						
Other Genotoxic Effects						
Repeat dose (14-day)						
Teratogenicity						
Acute Avian Oral – Quail/Duck						
Avían Dietary – Quail						
Fish toxicity - Bluegill						
Fish Toxicity - Rainbow Trout						
Invertebrate Toxicity						
MENTAL FATE						
Hydrolysis						
	Address: C. PO Box 3650, Grapevine, TX 76051 (PC code 40503) Guideline Study Name Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral – Quail/Duck Avian Dietary – Quail Fish toxicity - Bluegill Fish Toxicity - Rainbow Trout Invertebrate Toxicity MENTAL FATE	Address: C. PO Box 3650, Grapevine, TX 76051 (PC code 40503) Guideline Study Name Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral – Quail/Duck Avian Dietary – Quail Fish toxicity - Bluegill Fish Toxicity - Rainbow Trout Invertebrate Toxicity MENTAL FATE	DATA MATRIX FOR ACTIVE INGREDIENT EPA Reg. No./File Symbol Address: Product Aloe Herbal Horse Spra PC code 40503) Guideline Study Name MRID Number Submitter Product Identity, Composition, and Analysis Physical/Chemical Properties DGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral – Quail/Duck Avian Dietary – Quail Fish Toxicity - Rainbow Trout Invertebrate Toxicity MENTAL FATE	BATA MATRIX FOR ACTIVE INGREDIENT EPA Reg. No./File Symbol 66962- Address: Product Aloe Herbal Horse Spray PC code 40503) Guideline Study Name MRID Number Submitter Status Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral – Quail/Duck Avian Dietary – Quail Fish Toxicity - Rainbow Trout Invertebrate Toxicity Invertebrate Toxicity Invertebrate Toxicity Invertebrate Toxicity MENTAL FATE		

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Signature Cothural

Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc.

Date |-4-07



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<i>'</i>	DATA MATRIX FOR ACTIV	'E INGREDIENT	ф.,		
Date January 4, 2007		EPA Reg. No./File Symt	001 56963-	Page 2 of 2	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 7	76051	Product Aloe Herbai Horse Spray			
Ingredient(s): Eucalyptus Oil (PC code 40503)					
deline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note	

FOOTNOTES



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Signature Atherine Rice, Agent for Espree Animals Products, Inc.

| Date | 1-9-07 |



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	. DATA M	ATRIX FOR ACTIV	/E INGREDIENT		
Date January 4, 2007			EPA Reg. No./File Symbol 66	Page 1 of 2	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Product Aloe Herbal Horse Spray			
Ingredient(s): Eucalyptus Oil	(PC code 40503)				
C Ideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-	Product (dentity, Composition, and				
62-	Analysis				
63-	Physical/Chemical Properties				
TOXICOL	OGY			· · · · · · · · · · · · · · · · · · ·	·
81-1	Acute Oral Toxicity	-		-	Waiver Request (1)
81-2	Acute Dermal Toxicity	-		-	Waiver Request (1)
81-3	Acute (nha)ation Toxicity	-		-	Waiver Request (t)
81-4	Primary Eye Irritation	-		-	Waiver Request (t)
81-5	Primary Dermal Irritation	-		-	Waiver Request (1)
81-6	Skin Sensitization	-		-	Waiver Request (1)
84-2A	Gene Mutation (Ames Test)			-	Waiver Request (1)
84-2B	Structura) Chromosomal Aberration	-		+	Waiver Request (1)
84-4	Other Genotoxic Effects	-		-	Waiver Request (1)
152-11	Repeat dose (14-day)	-		-	Waiver Request (2)
152-23	Teratogenicity	-		-	Waiver Request
ECOLOGI	CAL EFFECTS				
71-1A	Acute Avian Ora(- Quail/Duck	+		-	Waiver Request (1)
71-2A	Avian Dietary – Quail	-		*	Waiver Request (1)
72-1A	Fish toxicity - Bluegi)l	-			Waiver Request (1)
72-1C	Fish Toxicity - Rainbow Trout	-		<u>-</u> .	Waiver Request (1)
72-2A	Invertebrate Toxicity	-		-	Waiver Request (t)
ENVIRON	MENTAL FATE				
161-1	Hydrolysis	-		-	Waiver Request (1)

	3			 			
Signature	I_c	1	h		THE POST TOWNS	Name and Title: Catherine Rice,	Date
. /	L ui :	1111	八			Agent for Espree Animals Products, Inc.	11-4-01
		VV		 			



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Do not send the form to this address.					
DATA	MATRIX FOR ACTIV		1.6		
Date January 4, 2007		EPA Reg. No./File Symbol	63960 -	Page 2 of 2	
Applicant's/Registrant's Name & Address:	Product &				
Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051	Aloe Herbal Horse Spray				
Ingredient(s): Eucalyptus Oil (PC code 40503)					
Guideline Reference Number Guideline Study Name	Submitter	Status	Note		
				· · · · · · · · · · · · · · · · · · ·	

JTNOTES

- Per pages 63 and 64 of the Flower and Vegetables Oils RED, the ecological effects, toxicology, and environmental fate generic data can be waived.
- Waiver requested since the proposed end-use product will be for non-human use.

Eucalyptus oil (CAS Reg. No. 8000-48-4, OPP chemical code 40503) is covered by the December 1993 Flower and Vegetable Oils RED. Page 7 of the RED addresses the use profile:

Type of Pesticide: repellent and insect feeding depressant

Use Sites: pets Target pests: fleas

Formulation types registered: impregnated material (collar)

Method and Rates of application Equipment – by hand

Method and Rate - up to one ounce per animal

Timing - as needed

Use Practice Limitation: none

duct covered by RED is end-use product at 1.00%.

The proposed product will be used a fly repellent to be used on horses. The percent of Eucalyptus oil will be 0.378%.

Rationale for Waiver Request: The use pattern addressed in the RED is slightly different from the proposed product's use pattern. However, both will be used on non-humans (pets vs. horses) to repel nuisance insects (fleas vs. flies). Further the RED covers end-use products rates at 1.00%. In the concentrated form, Aloe Herbal Horse Spray contains 0.378% eucalyptus oil. According to the product's use directions, this product is then to be diluted with a minimum of 4 parts water. Thus, the end use will contain 0.095% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic ecological effects, toxicology, and environmental fate data requirements can be waived.

Signature/ ; ,	Name and Title: Catherine Rice,	Date
(lithin-1	Agent for Espree Animals Products, Inc.	/-4-07
EDA C 0070 OF ID D71 Flavore C.		

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		DATA MA	ATRIX FOR End	-Use Product 🥏 🤲 💯			
Date Jan	uary 4, 2007	,	EPA Reg. No./File Symbol 766	Page 1 of 2			
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray				
naredient(s):	Citronella Oil (F	PC code 021901), Cedarwood Oil (PC code 405	05), Eucalyptus Oil	(PC code 40503)			
Jeline Ret	ference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830	0.1550	Product Identity and Composition					
830	0.1600	Description of the Materials Used to Produce the Product					
830	0.1650	Description of the Manufacturing Process					
	0.1670	Discussion of Formation of Impurities					
830	0.1700	Preliminary Analysis					
830	0.1750	Certified Limits					
	0.1800	Enforcement Analytical Method					
hysical/Che	emical						
roperties							
	0.6302	Color					
	0.6303	Physical State					
	0.6304	Odor					
	0.6314	Oxidation/Reduction Chemical Incompatability					
	0.6315	Flammability					
	0.6316	Explodability					
	0.6317	Storage stability					
	0.6319	Miscibility					
	0.6320	Corrosion characteristics					
	0.632 t	Dielectric breakdown voltage					
	0.7000	pH					
	0.7100	Viscosity					
83	0.7300	Density/Relative Density	<u> </u>				
87	0.1100	Acute Oral Toxicity					
	0.1200	Acute Dermal Toxicity					
	0.1200	Acute Inhalation Toxicity					
	0.2400	Primary Eye Irritation					
87	0.2500	Primary Dermal Irritation	<u> </u>				

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Name and Title: Catherine Rice Agent for Espree Animal Products, Inc. Date / -4.07



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DATA MATRIX FOR End-Use Product

Date January 4, 2007			EPA Reg. No./File Symbol 66963- Page 2 of 2			
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
Ingredient(s): Citronella Oil (F	PC code 021901), Cedarwood Oil (PC	code 40505), Eucalyptus Oil	(PC code 40503)			
(sline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
870.2600	Skin Sensitization					
EFFICAC'	Y					
96-9	Product Performance					

OOTNOTES



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Signature athur - N

Name and Title: Catherine Rice Agent for Espree Animal Products, Inc.

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7-4-07



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	√ DATA N	IATRIX FOR ACTIV	/FINGREDIENT -	કર્ય : ઇલ			
Date January 4, 2007			EPA Reg. No./File Symbol su66563-				
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray				
tnaredient(s): Oit of citronella	(PC code 021901)						
aline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
151B-10 – 151B-15	Product Identity, Composition, and Analysis						
151B-17	Physical/Chemical Properties			<u></u>			
TOXI C OLO							
152B-1 0	Acute Oral Toxicity						
152B-11	Acute Dermal Toxicity						
152B-12	Acute Inhalation Toxicity						
152B-13	Primary Eye Irritation						
152B-14	Primary Dermal Irritation						
152B-15	Dermal Sensitization						
152B-16	Hypersensitivity						
152B-17	Microbial mutagenicity						
152B-18	Immunotoxicity						
152B-2 0	90-Day oral toxicity						
152B-21	90-Day dermal toxicity				<u></u>		
152B-23	Developmental Toxicity						
→ ECOLOGI	CAL EFFECTS						

Signature

Signature athur n

Name and Tille: Catherine Rice, Agent for Espree Animal products, Inc. Date /-4 ()')

DATA PACKAGE BEAN SHEET

Date: 04-Apr-2007 Page t ot 3 Decision #: 373758 DP #: (338682)

PRIA

Parent DP#:

* * * Registration Information * * *

Registration:	66963-I - ALOE	HERBAL HORSE SPRA	Υ				
Company:	66963 - ESPREE A	NIMAL PRODUCTS, INC					
Risk Manager:	RM 9t - Driss Benm						
Risk Manager Reviewer:	Todd Peterson TPE	Todd Peterson TPETERSO					
Sent Date:		Calculated Due Da	te: 14-Jun-2007	Edite	d Due Date:		
Type of Registration;	Product Registration	- Section 3					
Action Desc:	(B67) NEW PRODU	CT;NON-FAST TRACK;MICRO	BIAL/BIOCHEMI	CAL;			
Ingredients:	See page 3				_		
	*	* * Data Package In	formation	* * *			
Expedite:	◯ Yes ● No	Date Se	ent: 04-Apr-2007	Passas.	Due Back:		
DP Ingredient:	See page 3				<u></u>		
DP Title:	Product Chem and	fox 6 Pack			···········		
CSF Included:	Yes No	Label Included: Yes	○ No Par	ent DP #:	_		
Assigned To	<u> </u>	Date in	Date Out				
Drganization: BPPD	/ BPB			Last Possible Scienc	e Due Date: <u>t4-Feb-2007</u>		
Team Name:				Scienc	e Due Date:		
				Sub Data Packag	e Due Date:		
Team Name:				Scienc	e Due Date:		

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product chemistry and Tox six pack for old active ingredients in new end use product. Please review data packages attached, CSF and related label language in relation to submitted data. Todd Peterson 703-308-7224

DP#: (338682)	* * * Studies Sent for Review * * *	Decision#: (373758)
MRID MRID Status	Citation Reference	Guideline
47029301	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition Source Active Ingredients. Unpublished study prepared by Espree Animal Products, Inc. 31 p.	830. t 550/Product Identity and composition
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.1550/Product Identity and composition
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.1600/Description of materials used to produce the product
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.1650/Description of formulation process
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.1670/Discussion of formation of impurities
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.1700/Preliminary analysis
47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared by Espree Animal Products, Inc. 50 p.	830.t750/Certified limits
47029303	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Wavier Request for Enforcement Analytical Method and Storage Stability. Unpublished study prepared by Espree Animal Products, Inc. 9 p.	
47029303	Lewis & Harrison, LLC (2007) Afoe Herbal Horse Spray: Wavier Request for Enforcement Analytical Method and Storage Stability. Unpublished study prepared by Espree Animal Products, Inc. 9 p.	830.6317/Storage stability of product
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.6303/Physical state
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.6314/Oxidizing or reducing action
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density, Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830,6320/Corrosion characteristics
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7000/pH of water solutions or suspensions
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7100/Viscosity
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	830.7300/Density/relative density
47029305	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Oral Toxicity Up and Down Procedure in Rats. Project Number: 21101, P320/UDP. Unpublished study prepared by Product Safety Laboratories. 14 p.	870.1100/Acute Oral Toxicity

DP#; (338682)	* * * Studies Sent for Review * * *	Decision#: (373758)
MFIID MFIID Status	Citation Reference	Guideline
47029306	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Dermal Toxicity Study in Rats - Limit Test. Project Number: 21102, P322/RAT. Unpublished study prepared by Product Satety Laboratories. 14 p.	870.1200/Acute dermal1oxicity
47029307	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Inhalation Toxicity Study in Rats - Limit Test. Project Number: 21103, P330. Unpublished study prepared by Product Safety Laboratories. 22 p.	870.1300/Acute inhalation toxicity
47029308	Durando, J. (2006) Aloe Herbal Horse Spray: Primary Eye Irritation Study in Rabbits. Project Number: 21t04, P324. Unpublished study prepared by Product Safety Laboratories. 17 p.	870.2400/Acute eye irritation
47029309	Durando, J. (2006) Aloe Herbal Horse Spray: Primary Skin Irritation Study in Rabbits. Project Number: 21105, P326. Unpublished study prepared by Product Safety Laboratories. 15 p.	870.2500/Acute dermal irritation
47029310	Durando, J. (2006) Aloe Herbal Horse Spray: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 21106, P328. Unpublished study prepared by Product Satety Laboratories. 23 p.	870.2600/Skin sensitization

Page 3

DP#: (3386	82)	*** ProdL and Data Package ingredients ***	Decision#: (373758)
PC Code	CAS	Ingradient Name	
0 t t550	42822-86-6	Cyclohexanemethanol, 2-hydroxy-alpha., alpha., 4-trimethyl-	
02190 t	8000-29-1	Oil of citronella	
040505	8000-27-9	Cedarwood oil	
0 t t550	42822-86-6	Cyclohexanemethanol, 2-hydroxy-,alpha., alpha.,4-1rimethyl-(.378%)	
040505	8000-27-9	Cedarwood oil(.5%)	
021901	8000-29-1	Oil of citronella(.75%)	

BPPD SCREEN PACKAGE

A.i.
BPPD FRONT END: BPB/MPB: Team Leader: 1. Colc
Pria Code/Action Code: B67 Team/RAL:
Product Name: Aloc Her bal Horse Spray
EPA ID No.: 6/3963 - I
Active Ingredient(s): Cyclo hexanemethanot; Cedarwood oil. Oil of
Food New Submission CITTON CITY
Non Food Reseubmission
Date In BPPD:
Date To Screen: 1/24/07
Date Expected From Screen: (10 days from date in): 2/4/07 WA#06-70
Nasrin Begum: Nasrin Begumet. Hours 4 Return to BPPD: 3/9/07
Received Date from Contactor: 3/9/07 Phases
SCREEN PACKAGE NOTES:
Pre- Reg Meetings attached? Yes No
Submission complies with all applicable areas of checklists? Indicate in detail on checklists forms when returned.
Additional Comments per Team Leader or Screener:
SCREEN STATUS
Administrative: Pass Fail
Scientific: PassFail



122 C Street, N.W., Suite 740 Washington, D.C. 20001

telephone 202,393,3903 fax 202,393,3906

Consultants in Government Affairs

January 4, 2007

HAND DELIVERED

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

To: Todd Peterson, Ph.D. (7511P)

Biopesticides and Pollution Prevention Division (BPPD)

RE: Registration Application for a New End-Use Product

Product: Aloe Herbal Horse Spray

EPA File Symbol: 66963-

Registrant: Espree Animal Products, Inc.

PRIA Category B72, New Product, Me-Too, Non-Fast Track

PRIA Fee is \$0 (100% Fee Waiver Request)

Dear Dr. Peterson:

On behalf of Rhodia Inc., I am submitting a registration application for **Aloe Herbal Horse Spray**, a new-use product. As mentioned at our September 2006 pre-submission meeting, this product contains three active ingredients: citronella oil, cedarwood oil, and eucalyptus oil.

PRODUCT CHEMISTRY DATA

Aloe Herbal Horse Spray uses three unregistered actives to formulate this product. As mentioned at the pre-submission meeting, we are supplying certificates of analysis on these source materials (please refer to Volume 1).

The three actives in this product are all essential oils. Since none of these materials is a discrete chemical, product analysis for each active (when used in combination) cannot be performed. Thus, we are requesting a waiver for the enforcement analytical method and the one-year storage stability. This waiver request is attached as Volume 3.

TOXICOLOGY

Espree is submitting product-specific acute toxicology studies to support this registration. These are being submitted as Volumes 5-10.

LABELING

Espree is current labeling is for an indoor, non-food use product.

EFFICACY

No public health claims are being proposed for this product; therefore no efficacy is required.

In support of this application, please find enclosed the following documents:

- 1) Small Business Waiver Request
- Application for Pesticide Registration form.
- 3) One (1) copy of the Confidential Statement of Formula (CSF) form for both a basic and alternative formulation.
- 4) Five (5) copies of the proposed product label.
- 5) Certification with Respect to Data Compensation form.
- 6) Data Matrix Chart for each of the active ingredients.
- 7) Product-Specific Data Matrix Chart.
- 8) Three (3) copies of the Summary of the Physical/Chemical Properties worksheet.
- 9) Three (3) copies of the Product Chemistry and Acute Toxicology data volumes.

Lewis & Harrison is acting on behalf of Espree as both the "Company Agent" and "Contact Point". Accordingly, please relay all questions and correspondence, including notification of the MRID numbers and Data Evaluation Records, directly to us.

If you have any questions about this submission, please contact either Eliot Harrison at (202) 393-3903 ext. 14 or me at (202) 393-3903 ext. 13.

Sincerely,

Catherine Rice

Agent for Espree Animal Products, Inc.

Administrative Material Screening Checklist

Date:3/9/07

EPA Reg. No.: 66963-I: B-67

Active ingredient name: Cedarwood oil, Oil of citronella, Eucalyptus oil Division RAL assigned (if any):

PASS

Admin Materials	Signed		Date Abs Con		Comments
	Yes	N o			
Form 8570-1 CSF - Completely filled out & original signature (EPA form 8570-4) inerts cleared? conventional or antimicrobial actives present in formulation? accurate information provided for suppliers/source? CSF accurately reflects label? Additional brand name listed in CSF note all comments	X	Available and the second secon	t/4/07	The state of the s	 Application is for a new product use Three unregistered active ingredients used to formulate the product Eucalyptus oil, cedar oil and citronella oil has numerous brand names; but not listed in the CSF CSF reflects label
Label legible product label? label accurately reflects csf? note all comments					Yes
Physical address of manufacturer on label to include EPA Establishment #	7070				Yes, EPA est. #66963-TX- 0 01
Data Matrix - Two/one for jacket; one for FOIA (EPA Form 8570-35) supports method of support? reflects information reported in transmittal document and company cover letter? note all comments	х		1/4/07	The state of the s	-yes -yes
Formulator's exemption form (EPA form 8570-27)				777798000000000000000000000000000000000	Not present , not applicable

Admin Materials	Signed	Date	Abs ent	Comments
Transmittal letters accurately reflects what is reported on data matrix? note all comments	×	t/4/07		
Petition/amended petition if food tolerance or exemption/amended food tolerance or exemption petition# assigned? petition jacket included? petition complete with sections A-G? note all comments - if there is not evidence of a petition # assigned and sect. A-G not present, package fails.			X	Non-food use, not applicable
FR template if food tolerance or exemption/amended food tolerance or exemption notice of filing template (disk) included? note all comments - a NOF must be present to establish a new tolerance exemption. Amendments to an existing tol. petition may be Agency initiated in which case a NOF would not expected to be present. (If unsure, check with branch team leader) component in the formulation not cleared food use		THE PROPERTY OF THE PROPERTY O	TOTAL PARTITION OF THE	Not applicable.
Certification with Respect to Citation of Data Form (EPA Form 8570-34) - if required. State method of support and indicate the EPA reg. # of the cited product if applicable.	X	t/4/07	T TET AMBROVAL TO THE TABLE	Selective method with cite-all option. Offer to pay. List of data submitters included in the package.
Minutes on data requirements (pre- registration meeting)	T. T			
Active ingredient # (i.e. Chemical PC code) more than one active? are all actives housed in BPPD?	THE STATE OF THE S		77.77.77.77.77.77.77.77.77.77.77.77.77.	Eucalyptus oil: 840503; Oil of Citronella:021901; Cedar oil:040505

Admin Materials	Signed	Date	Abs ent	Comments
Jacket from EPA Identifying Symbol				66963-I
Are MRIDS assigned? (State Yes/No in comments)				Yes
Background Experimental Use Permit information, if applicable request for temporary tol. exempt, tol. exempt, tol. exemption or numeric tolerance? note all comments refer to petition and fr section for critera.				Not applicable

Rev. 2/27/07

CHECKLIST FOR DATA PACKAGE SCIENCE SCREEN

Active Ingredients and PC codes: Eucalyptus oil: 840503; Oil of Citronella: 021901; Cedar oil:

040505

Product Name: Aloe Herbal Horse Spray

EPA Reg. No/File Symbol: 66963-I

Petition # (if applicable):

	Circle or Cl	neck App	propriat	te Boxes)
		Prod	uct Typ	e
ochemical, Microbial, or PIP		В	M	P
od Use		N		
raight-chain Lepidopteran Pheromone iochemical Only)		N		
ew Active Ingredient		N		
c. 3 Registration		Y		
perimental Use Permit		N		
-4 Submission		Ŋ		
ethyl Bromide Alternative		N		±
duced Risk Product		Y		
	Prod	luct Spec	cific Inf	formation
ata Requirement	TGAI	MP	EP	
oduct Label			Y	
		Produc	t Cliemi	istry
3F			Y	Yes, complete
oduct Identity & Composition			Y	Study submitted in MRID#470293-01
anufacturing Process			Y	Study submitted in MRID#470293-02
escription of the Formation of appurities			Y	Study submitted in MRID#470293-02
eliminary Analysis				Study submitted in MRID#470293-02
ertified Limits			Y	Study submitted in MRID#470293-02
oforcement Analytical Methods				Study submitted in MRID#470293-03
nysical/Chemical Properties (as shown 40 CFR 158.190 Table)			Y	Study submitted in MRID#470293-04

Tier I Toxicity (If n	o study, indicate in	Comments if waiver submitted)
cute Oral	Y	Study submitted in MRID#470293-05
cute Dermal	Y	Study submitted in MRID#470293-06
cute Inhalation	Y	Study submitted in MRID#470293-07
C., I.P., I.V. Injection (Microbial dy)		
imary Dermal Irritation	Y	Study submitted in MRID#470293-09
imary Eye Irritation	Y	Study submitted in MRID#470293-08
ypersensitivity Conditionally required)	Y	Study submitted in MRID#470293-10
ypersensitivity Incidents onditionally required)		
enotoxicity Studies (Biochemical lly)	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED
umune Response	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED
ssue Culture ficrobial only)		
-day Feeding iochemical only)		Waiver requested in pp 21-22 of the Cedar wood oil RED
-day Dermal iochemical only)		Waiver requested in pp 21-22 of the Cedar wood oil RED
-day Inhalation iochemical only)		Waiver requested in pp 21-22 of the Cedar wood oil RED
ratogenicity/developmental toxicity iochemical only)		Waiver requested in pp 21-22 of the Cedar wood oil RED
Tier I Non-Target Organism	ıs (If no study, ind	icate in Comments if waiver submitted)
rian Acute Oral	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED
rian Acute Dietary	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED
eshwater Fish LC50	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED

eshwater Invertebrate LC50	Y	Waiver requested in pp 21-22 of the Cedar wood oil RED
on-target Plants		
on-Target Insects		
oneybee Testing ficrobials only)		
Other Studies [As rec	nired by product specific	data requirements(e.g. efficacy, residues)
ficacy study		Not present

Science Screen Comment Form

Active Ingredients and PC codes: Eucalyptus oil: 840503; Oil of Citronella: 021901; Cedar oil:

040505

Product Name: Aloe Herbal Horse Spray

RAL:

Status: PASS

THIS FORM DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Product Chemistry:

Data requirement is addressed by submitted studies appears to be adequate. Waiver request made for Enforcement analytical method and storage ability seems to be justified. For details please see above form.

Toxicity:

Data requirement is addressed by submitted studies request seems to be adequate and justified.

Non-target Organisms/ Environmental Fate:

Data requirement is addressed by cited waiver request appears to be justified.

Product Performance (Efficacy):

Not performed. Justification provided as "as no public health pest claim present' that is why not performed.

Residue:

Not present. Not required (non food, feed)

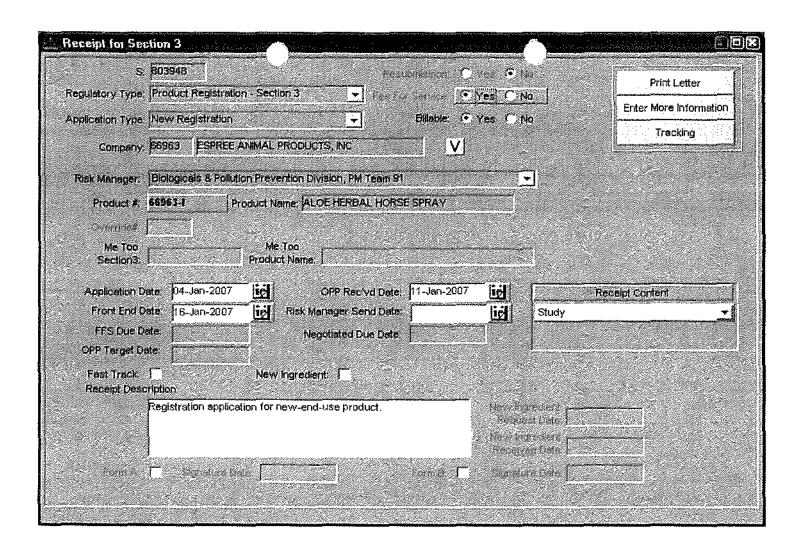
Other non guideline or supplemental information:

Comments/Recommendations:

Caution: No efficacy study

MEMORANDUM

DATE: DI	/19/02				
T0:	PM	9)	, Regula	tory Mana	äger
FROM: Inf	ormation	Services	Branch	, ITRMD	
Your r indication have beer		Ds for th	e enclo		
We ex from the a is available		te befor		_	•
If you lolease con	have any tact Tere				cess,
his is a:	🗖 partia	iccepted Ily accep ed subm	oted sub		



FEE FOR SERVICE

NEW APPLICATIONS

DATE:	JAN 1 1 2007		
FILE NU	MBER: _ 66	963-I	
FEP (OPI	PIN ENTRY	(Init	1/16/07 ial & date)
FILE RO		al & da	
SIG: $\frac{4}{\sqrt{1}}$	C ///8/ nitial & date	<u>/₀₇</u>	
FILE RO	OM: <u>04 /</u> (Initi	19.07 ial & da	ite)
✓ ASSI	GN TO PM	-91	(NO DATA)
JAC	KET TO SI	HELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

January 17, 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-373758

EPA File Symbol or Registration Number: 66963-I Product Name: ALOE HERBAL HORSE SPRAY

EPA Receipt Date: 11-Jan-2007 EPA Company Number: 66963

Company Name: ESPREE ANIMAL PRODUCTS, INC

CATHERINE RICE LEWIS & HARRISON, LLC ESPREE ANIMAL PRODUCTS, INC 122 C STREET, NORTHWEST, SUITE 740 WASHINGTON, DC 20001-

SUBJECT: Receipt of Registration Application and 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for registration and 100% small business waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B67

NEW PRODUCT; NON-FAST TRACK; MICROBIAL/BIOCHEMICAL;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely.

Front End Processing Staff

Information Technology & Resources Management Division



This package includes the following	for Division
New Registration	○ AD
○ Amendment	
Studies?	Risk Mgr. 91
volpay % Reduction:	
Receipt No. S-	803948
EPA File Symbol/Reg. No.	66963-I
Pin-Punch Date:	1/11/2007
i iii-i uiicii Dale.	1/11/2007
☐ This item is NOT subject to	FFS action.
Action Code:	Parent/Child Decisions:
Requested: 1372	
Granted: Bb7	
Amount Due: \$ 4200	
Reviewer: Say	Date: 1//6/07

Please read instructions on	reversa before c	ting form.	F	orm Appr	OMB No. 20	70-006	D. Approvel expires 2-28-9
\$EPA	Environmental	Inited States I Protection ngton, DC 2046	- .	V	Registrat Amendm Other		OPP Identifier Number
948		Application	n for Pesticide -	Section	1	······································	
1. Company/Product Numbe 66963-	r		2. EPA Produ	ict Manager		_	oposed Classification
4. Company/Product [Nome] Aloe Herbal Ho/se Spr			PM# BPPD (11			
5. Name and Address of Ap Espree Animal Proc 3250 Stone Myers F Grapevien, TX 76-5	lucts, Inc.	vine Ti	(b)(i), my pr to: EPA Reg. Product N	oduct is sim	nilar or identic	al in col	FIFRA Section 3(c)(3) mposition and labeling
· · · · · · · · · · · · · · · · · · ·			Section - II				
Amendment - Explair Resubmission in resp Notification - Explein	ionse to Agancy letter	dated	Ago "Me	il printed lebe ncy letter dat i Too" Applic or - Explain be	ation.	to	
Registration application for n PRIA Category B7 2, New, Pr PRIA F ee is \$0 (100% lee w	roduct, Non-Fast Track.		er for details. Section - III				
Material This Product Will	Ba Packaged in:		Section - III				
Child-Resistant Packeging Yes No	Unit Peckaging Yes V No		Water Soluble Packer Yes No	ping	V	ontainer Metel Plastic Glass	
* Certification must be submitted	if "Yes" Unit Packaging wgt.	No. per conteiner		o. per ontainor		Paper Other (S	pecify)
3. Location of Ner Contants	Information ontainer	4. Sizelsi Retai 4 fl. oz, 32 f	l Container I. oz., 128 fl. oz (1 gal	l r	cetion of Lebel On Label	Oirectio	ns
6. Manner in Which Label is	Affixed to Product	Lithogra Paper of Stenciled	ph uod d	Other			
			Section - IV				
1. Contact Paint /Complete	items directly below fo	or identification	of individual to be cont	lacied, if nec	essary, to proc	ess this	application.)
Name Eliot Hattison		1	itle Agent fo r Esp ree Anim	nal Product,		-	No. Ilncluda Aree Code) 903 x 14
I certify that the stater I acknowledge that end both under applicable t	y knowlingliy falsa or n		ll ettachments thereto		, ,	- 1	6, Date Application Received (Stamped)
2. Signature	N:		Title Agent for Espree Animal	Products, Inc			,,,,,,,
4. Typed Name Catherine Rice			0ere 1-4-07				218



122 C Street, N.W., Suite 740 Washington, D.C. 20001 telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs

January 4, 2007

HAND DELIVERED

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

To: Todd Peterson, Ph.D. (7511P)

Biopesticides and Pollution Prevention Division (BPPD)

RE: Registration Application for a New End-Use Product

Product: Aloe Herbai Horse Spray

EPA File Symbol: 66963-

Registrant: Espree Animal Products, Inc.

PRIA Category B72, New Product, Me-Too, Non-Fast Track

PRIA Fee is \$0 (100% Fee Waiver Request)

Dear Dr. Peterson:

On behalf of Rhodia inc. I am submitting a registration application for Aloe Herbal Horse Spray, a new-use product. As mentioned at our September 2006 pre-submission meeting, this product contains three active ingredients: citronella oil, cedarwood oil, and eucalyptus oil.

PRODUCT CHEMISTRY DATA

Aloe Herbal Horse Spray uses three unregistered actives to formulate this product. As mentioned at the pre-submission meeting, we are supplying certificates of analysis on these source materials (please refer to Volume 1).

The three actives in this product are all essential oils. Since none of these materials is a discrete chemical, product analysis for each active (when used in combination) cannot be performed. Thus, we are requesting a waiver for the enforcement analytical method and the one-year storage stability. This waiver request is attached as Volume 3.

Page 1 of 2 219

TOXICOLOGY

Espree is submitting product-specific acute toxicology studies to support this registration. These are being submitted as Volumes 5-10.

LABELING

Espree is current labeling is for an indoor, non-food use product.

EFFICACY

No public health claims are being proposed for this product; therefore no efficacy is required.

In support of this application, please find enclosed the following documents:

- 1) Small Business Waiver Request
- 2) Application for Pesticide Registration form.
- 3) One (1) copy of the Confidential Statement of Formula (CSF) form for both a basic and alternative formulation.
- 4) Five (5) copies of the proposed product label.
- 5) Certification with Respect to Data Compensation form.
- 6) Data Matrix Chart for each of the active ingredients.
- 7) Product-Specific Data Matrix Chart.
- 8) Three (3) copies of the Summary of the Physical/Chemical Properties worksheet.:.
- 9) Three (3) copies of the Product Chemistry and Acute Toxicology data volumes. 🗼

Lewis & Harrison is acting on behalf of Espree as both the "Company Agent" and "Contact Point". Accordingly, please relay all questions and correspondence, including notification of the MRID numbers and Data Evaluation Records, directly to us.

If you have any questions about this submission, please contact either Eliot Harrison at (202) 393-3903 ext. 14 or me at (202) 393-3903 ext. t3.

Sincerely,

Catherine Rice

Agent for Espree Animal Products, Inc.



122 C Street, N.W., Suite 740 Washington, D.C. 20001 telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs

January 4, 2007

HAND DELIVERED

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

To: Todd Peterson, Ph.D. (7511P)

Biopesticides and Pollution Prevention Division (BPPD)

RE: Registration Application for a New End-Use Product

Product: Aloe Herbal Horse Spray

EPA File Symbol: 66963-

Registrant: Espree Animal Products, Inc.

Data Transmittal Letter for Studies Supporting the Registration Application

of Aloe Herbal Horse Spray

Dear Dr. Peterson:

On behalf of Espree Animal Products, Inc., I am submitting three (3) copies of the following studies in support of the Section 3 registration application for Aloe Herbal Horse Spray:

- Volume 1 of 10
 - Aloe Herbal Horse Spray: Product Identity and Composition Source Active Ingredients. January 3, 2007. 31 pp. MRID#
- Volume 2 of 10

Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. January 3, 2007. 4 pp. and 46 conf. pp. MRID#

Page 1 of 3 22

- Volume 3 of 10
 Aloe Herbal Horse Spray: Wavier Request for Enforcement Analytical Method and Storage Stability. January 3, 2007. 9 pp.

 MRID#
- Volume 4 of 10
 Physical and chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity, and Relative Density. November 28, 2006.

 Performing Laboratory: Case Consulting Laboratories, Inc. 7 pp. MRID#
- Volume 6 of 10
 Acute Dermal Toxicity Study in Rats Limit Test. December 20, 2006
 Performing Laboratory: Eurofins/Product Safety Laboratory. 14 pp.
 MRID #:
- Volume 7 of 10
 Acute Inhalation Toxicity Study in Rats Limit Test. December 20, 2006
 Performing Laboratory: Eurofins/Product Safety Laboratory. 22 pp.
 MRID #:
- Volume 8 of 10
 Primary Eye Irritation Study in Rabbits. December 20, 2006

 Performing Laboratory: Eurofins/Product Safety Laboratory. 17 pp. MRID #:
- Volume 9 of 10
 Primary Skin Irritation Study in Rabbit. December 20, 2006

 Performing Laboratory; Eurofins/Product Safety Laboratory. 15 pp. MRID #;

Volume 10 of 10
 Dermal Sensitization Study in Guinea Pigs (Buehler Method). December 20, 2006

 Performing Laboratory: Eurofins/Product Safety Laboratory. 23 pp. MRID #:

If you have any questions about this submission, please contact either Eliot Harrison at (202) 393-3903 ext. 14 or me at (202) 393-3903 ext. 13.

Sincerely.

Catherine Rice

Agent for Espree Animal Products, Inc.



UNLED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average I hour per response for registration activities and I hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)), U. S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to his address.

SUMMAR	RY OF THE PHYSI	CAL/CHEMICAL	PROPERTIES (PR N	otice 98-1)	
t. PRODUCT NAME:	2. Reg. No.				
Aloe Herbal	66963- (not yet assigned)				
3. COMPANY NAME:		711111111111111111111111111111111111111		4. SUBMISSION DATE:	
Espree Animal	Espree Animal Products, Inc.				
5. FIRST SUBMISSION [X] 6. RESUBMISSION []	t0. REGISTRATION [X]				
8. FORMULATED MANUFACT	URING-USE PRODUC	T or 9. END-U	SE PRODUCT X	[]. REREGISTRATION]	
13. PRODUCT MANAGER OR O Marshall Swindell, AD 1		MANAGER#/NAME	(IF KNOWN):	12. REREG CASE #	
14. GUIDELINE REFERENCE NO.(GRN)/TtTLE	15. VALUE or QUA WHE	LITATIVE DESRIPTION RE APPLICABLE AND I	N/METItOD(s) USED REFERENCES	16. MRID or REPORT NO.	
Group	B, Series 830-Phys	sical and Chemical	Properties (40CFR 15	8.190)	
- 6302 Color	Clear, eoloricss		Not yet assigned		
- 6303 Physical State	Liquid			Not yet assigned	
- 6304 Odor	Not Required - per	PR Notice 95-2			
- 6314 Oxidation/Reduction Chemical Incompatibility	Exposure System Powdered Iron	Upon Mixing No signs of	After 24 hours exposurc No signs of reaction	Not yet assigned	
		reaction			
	Potassium permanganate	No signs of reaction	No signs of reaction		
	Water	No signs of reaction	No signs of reaction		
	Monoammonium phospalc	No signs of reaction	No signs of reaction		
- 6315 Flammability/Flame Extension	Not Applicable sin combustible liquid		pray does not conlain any		
- 6316 Expledability	Not Applicable sind explosive ingredien		pray does not contain any		
- 6317 Storage Stability	Waiver requested i	inder 40 CFR 158.t55((f). Please refer to Volume		
- 6319 Miscibility			pray is not to be diluted	, 1100 г. 11	
- 6320 Corrosion Characteristics	**************************************	ntly being conducted.	Will be submitted on		
- 6321 Dieleetric Breakdown Voltage		ce Aloe Herlyal Horse S	pray is not for use around	ORDERON CONTROL OF THE PROPERTY OF THE PROPERT	
- 7000 pH	4.90 (25C)	**************************************		Not yet assigned	
-7t[] Vicosity	18.266 mm ² /s (cSt)	(22C)		Not yet assigned	
- 7300 Density/Relative Density/ Bulk Density	0.8435	7	: ;	Not yet assigned	

EPA Form 8570-36 (07/JAN/1998)



Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmentat Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MA	ATRIX FOR End-U	lse Product		
Date January 4, 2007	7		EPA Reg. No./File Symbol 66963-	Page 1 of 2	
Applicant's/Registrant's Na			Product		
Espree Animal Products	s, Inc. PO Box 3650, Grapevine, TX 76051		Aloe Herbal Horse Spray		
tananati antah Otto anatha O	27 (20 1- 204024)	NEL E			
	Dil (PC code 021901), Cedarwood Oil (PC code 4050	[
Guideline Reference Numb		MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	Not Yet Assigned	Espree Animal Products (66963) Espree Animal Products (66963)	OWN	Footnote 1, Volume 1 Volume 2
830.1600	Description of the Materials Used to Produce the Product	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 2
830.1650	Description of the Manufacturing Process	Not Yet Assigned	Espree Animal Products (66963)	OWN _	Volume 2
830.1670	Discussion of Formation of Impurities	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 2
830.1700	Preliminary Analysis	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 2
830.17 5 0	Certified Limits	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 2
830.1800	Enforcement Analytical Method	Waiver Requested	Espree Animal Products (66963)	OWN	Footnote 2, Volume
Physical/Chemical Properties					
830.6302	Color	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
830,6303	Physical State	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
830.6304	Odor			Not Required	Footnote 3
830.6314	Oxidation/Reduction Chemical Incompatability	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
830.6315	Flammability			Not Required	Footnote 4
830.6316	Explodability			Not Required	Footnote 4
830.6317	Storage stability	Waiver Requested	Espree Animal Products (66963)	OWN	Footnote 2, Volume
830.6319	Miscibility			Not Required	Footnote 4
830.6320	Corrosion characteristics	Pending			Footnote 5
830.6321	Dielectric breakdown voltage			Not Required	Footnote 4
830,7000	Ha	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
830.7100	Viscosity	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
830-7300	Density/Relative Density	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 4
PYXOT	COLOGY				
870.1100	Acute Oral Toxicity	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 5
870.1200	Acute Dermal Toxicity	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 6
070.1300	Acute Inhalation Toxicity	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 7
0.70.2406	Frimary Eye Imitation	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 8
870.2500	Primary Dermal Irritation	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume 9
Signature / !	- 1.		Name and Title: Catherine Rice		Date

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Agent for Espree Animal Products, Inc.



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Do not send the form to this addr	ess.					
	DATA MA	ATRIX FOR End	I-Use Product			
Date January 4, 2007			EPA Reg. No./File Sýmbol %66963;		Page t of 2	
Applicant's/Registrant's Name & Address: Espree Animal Products, tnc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
Ingredient(s): Citronella Oil (F	^{PC} code 021901), Cedarwood Oil (PC code 405	05), Eucalyptus Oil	(PC code 40503)			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830,1550	Product Identity and Composition					
830.1600	Description of the Materials Used to Produce the Product					
830.1650	Description of the Manufacturing Process			1		
830.1670	Discussion of Formation of Impunties					
830.1700	Preliminary Analysis					
830.1750	Certified Limits					
830.1800	Enforcement Analytical Method					
Physical/Chemical Properties						
830.6302	Color					
830.6303	Physical State					
830.6304	Odor					
830.6314	Oxidation/Reduction Chemical Incompatability					
830.6315	Flammability					
830,6316	Explodability					
830,6317	Storage stability					
830.6319	Miscibility					
830.6320	Corrosion characteristics					
830.6321	Dielectric breakdown voltage					
830.7000	PH	<u></u>				
830.7100	Viscosity					
830.7300	Density/Relative Density					
870,1100	Acute Oral Toxicity					
870.1200	Acute Dermal Toxicity					
870.1300	Acute Inhalation Toxicity					
870.2400	Primary Eye Irritation			1		
870.2500	Primary Dermal Irritation					
070.2000	() misary Dermai imitation	<u> </u>	<u> </u>	<u> </u>		

Signature

Cathur-A

Name and Title: Catherine Rice Agent for Espree Animal Products, Inc. Date / _4.0



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		DATA MATRIX FOR End-U	lse Product		
Date January 4, 2007	January 4, 2007				Page 2 of 2
Applicant's/Registrant's Name a Espree Animal Products, In	& Address: c. PO Box 3650, Grapevine, TX-760	51	Product Aloe Herbal Horse Spray		
Ingredient(s): Citronella Oil (F	PC code 021901), Cedarwood Oil (PC	code 40505), Eucalyptus Oil (F	C code 40503)		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.260 0	Skin Sensitization	Not Yet Assigned	Espree Animal Products (66963)	OWN	Volume t0
E FFICACY					
96-9	Product Performance	-			Not required, no human health claims

FOOTNOTES

- Information on the three source active ingredients is submitted as Volume 1.
- Waiver requested for the enforcement analytical method and storage stability since this product contains three essential oils in combination. The rationale for this waiver request is presented as Volume 2.
- 3 Per PR Notice 95-2, these studies are not required.
- These data requirements are not required, as described on the attached "Summary of Physical-Chemical Properties" worksheet.
- The one-year corrosion characteristics study is ongoing. The study will be submitted upon completion.

Signature // /	Name and Title: Catherine Rice	Date
(athur 1	Agent for Espree Animal Products, Inc.	1-4-07



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		DATA MATRIX FOR End	l-Use Product	₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩ ₩	
Date January 4, 2007 Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			EPA Reg. No./File Symbol	Page 2 of 2	
			Product Aloe Herbal Horse Spray		
Ingredient(s): Citronella Oil (F	PC code 021901), Cedarwood Oil (PC	C code 40505), Eucalyptus Oil	(PC code 40503)		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Nole
87 0 .2600	Skin Sensitization				
EFFICAC)	Y				
96-9	Product Performance				
		<u> </u>			

FOOTNOTES

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Signature /	100	l n	 	Name	and Title: Catherine Rice		Date
/	Uts	uu - 16		Agent	t for Espree Animal Products	, Inc.	1-4-07
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DATA MATRIX FOR ACTIVE INGREDIENT								
Date January 4, 2007		EPA Reg. No./File Symbol66463Page						
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray					
ingredient(s): Oil of citronella	(PC code 021901)							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note			
151B-10 – 151B-15	Product Identity, Composition, and Analysis							
151B-17	Physical/Chemical Properties							
TOXICOL								
152B-10	Acute Oral Toxicity							
152B-11	Acute Dermal Toxicity							
15 2 B-12	Acute Inhalation Toxicity							
152B-13	Primary Eye Irritation							
152B-14	Primary Dermal Irritation							
152B-15	Dermal Sensitization				:			
152B-16	Hypersensitivity							
152B-17	Microbial mutagenicity							
152B-18	Immunotoxicity			· · · · · · · · · · · · · · · · · · ·				
152B-20	90-Day oral toxicity							
152B-21	90-Day dermal toxicity							
152B-23	Developmental Toxicity							
ECOLOGI	CAL EFFECTS							

Signature athur n.

Name and Title: Catherine Rice, Agent for Espree Animal products, Inc.

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	DATA I	MATRIX FOR ACTIV	E INGREDIENT	 보조보면 보조기 (**) 보조보면 보조기 (**) 보조님 보조기 (**) 		
Date January 4, 2007	Date January 4, 2007			ວ່ ໄ ູ 665,63 -	Page 2 of 3	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray			
Ingredient(s): Oil of citronella	(PC code 021901)				-	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
154B-6	Acute Avian Oral					
154B-7	Avian Subacute Dietary Toxicity					
154B-8	Fish toxicity					
154B-9	Invertebrate Toxicity					
154B-10	Nontarget plants					
154B-11	Nontarget insects					
ENVIRON	MENTAL FATE					
	ALL					

FOOTNOTES

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Signature	/	athur	1	

Name and Title: Catherine Rice, Agent for Espree Animal products, Inc. Date /- (/-())



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DATA MATRIX FOR ACTIVE INGREDIENT								
Date January 4, 2007			EPA Reg. No./Fite Symb	ပ် ၂ 66 963-	Page 3 of 3			
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray					
Ingredient(s): Oil of citronell	a (PC code 021901)		······································	···········	- Marie - Mari			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note			

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Signature /	12		Name and Title: Catherine Rice,	Date / /
(U	thur W.	Agent for Espree Animal products, Inc.	1-9-07
		10000	1	•



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	DATA N	IATRIX FOR ACTIVE	INGREDIENT	w _w	
Date January 4, 2007		EPA Reg. No./File Symbol; * 66963-,		Page 1 of 3	
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray		
Ingredient(s): Oil of citronella	(PC code 021901)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151B-10 – 151B-15	Product Identity, Composition, and Analysis	41785703	Cand(e Corp (009201)	OLD	(1)
151B-17	Physical/Chemical Properties	41785703	Candle Corp (009201)	OLD	(1)
TOXICOL	OGY				
152B-10	Acute Oral Toxicity	41747402	Candle Corp (009201)	OLD	(1)
		43179401	Citronella Joint Venture (6773	36) PAY _	(3)
152B-11	Acute Dermal Toxicity	41747403	Candle Corp (009201)	OLD	(1)
		43167101	Citronella Joint Venture (6773	36) PAY _	(3)
152B-12	Acute Inhalation Toxicity	41747404	Candle Corp (009201)	OLD	(1)
		43167102	Citronella Joint Venture (6773	36) PAY _	(3)
152B-13	Primary Eye Irritation	41747405	Candle Corp (009201)	OLD	(1)
		43167103	Citronel(a Joint Venture (6773		(3)
152B-14	Primary Dermal Irritation	41747406	Candle Corp (009201)	OLD	(t)
		43167104	Citronella Joint Venture (6773		(3)
152B-15	Dermal Sensitization	41747407	Candle Corp (009201)	OLD	(1)
		43167105	Citronella Joint Venture (6773	36) PAY	· · · · · · · · · · · · · · · · · · ·
152B-16	Hypersensitivity				Not Applicable
152B-17	Microbial mutagenicity	41786701	Citronella Joint Venture (6773		(1)
		41785702	Citronella Joint Venture (6773		
		41747408	Candle Corp (009201)	OLD	
152B-18	Immunotoxicity	*			Waiver Request (
152B-20	90-Day oral toxicity	-			Waiver Request (
152B-21	90-Day dermal toxicity	<u> </u>		-	Waiver Request (
152B-23	Developmental Toxicity ICAL EFFECTS	<u> </u>		<u> </u>	Waiver Request (

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	/ 1		
Signature /	10 1	Name and Title: Catherine Rice,	Date
(Athin 112	Agent for Espree Animal products, Inc.	1-4-07



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	DATA 8	MATRIX FOR ACTIVE	INCOCNICAL		
	DAIA	WATRIA FOR ACTIVE	INGREDICITI	V	
Date January 4, 2007			EPA Reg. No./File Symboy * 66993-	* * * * * * * * ***	Page 2 of 3
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product 3444		
Lapree Ammai Froducts, in	C. PO DOX 3030, Grapeville, 1X 10031		Aloe Herbal Horse Spray		
Ingredient(s): Oil of citronella	(PC code 021901)				
Suideline Reference Number Guideline Study Name MRID Nu		MRID Number	Submitter	Status	Note
154B-6	Acute Avian Oral	41747409	Candle Corp (009201)	OLD	(1)
1548-7	Avian Subacute Dietary Toxicity	-		-	Waiver Request (2)
154B-8	Fish toxicity	41747410	Candle Corp (009201)	OLD	(1)
154B-9	Invertebrate Toxicity	41747411	Candle Corp (009201)	OLD	(1)
154B-10	Nontarget plants	-			Waiver Request (2)
154B-11	Nontarget insects	-			Waiver Request (2)
ENVIRON	MENTAL FATE				·
	TALL	_		-	Waiver Request (2)

FOOTNOTES

- Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been fulfilled.
- Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been waived.
- 3. The Data Submitters List (9/30/2006) does not list this company (67736) as a data submitter for oil of citronella. As a result, no offer to pay letter has been sent.

Citronella (CAS Reg. No. 8000-29-1, OPP chemical code 021901) is covered by the Oil of Citronella RED.

Page 2-3 pf the RED address the use profile:

Type of Pesticides - biochemical - insect and animal repellent

Use Sites:

Indoor nonfood: Animal treatment - horse-show/race/special, ponies

Indoor residential: human body/clothing while being worn (insect control); skin contact treatment, animal treatment (flea collar)

Outdoor residential: household/domestic dwelling outdoor premise use

Terrestrial non-food + outdoor residential: ornamental and/or share trees; ornamental herbaceous plants; ornamental woody shrubs and vines

Target Pests:

biting midges, biting flies, black flies, bugs, cats, deer flies, deer ticks, dogs, face flies, flying insects, gnats, horn flies, horse flies, house flies, insects, mosquitoes, "no-see-ums", stable flies

Formulation Types registered:

Signature / Ott / 1	Name and Title: Catherine Rice, Agent for Espree Animal products, Inc.	Date 1-4-07

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DATA MATRIX FOR ACTIVE INGREDIENT								
Date January 4, 2007	EPA Reg. No./File Symbol 66963-							
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051	Product Aloe Herbal Horse Spray							
Ingredient(s): Oil of citronella (PC code 021901)								
Guideline Reference Number Guideline Study Name	MRtD Number	Submitter	Status	Note				

Liquid ready to use, impregnates material, pelleted/tableted, impregnated collar/tag

Method and Rates of Application

Types of treatment: hand held sprayer, cloth wipe-on, candle, cartridge, rub-on, scent post application, sprinkle by hand, flea collar

Method and Rate: varies

Timing; as needed

Use Practice Limitations: None

The proposed product will be used a fly repellent to be used on horses. The percent of citronella oil will be 0.75%.

Rationale for Waiver Request: The use patterns addressed in the RED is includes a use that is almost identical the proposed use pattern (horses); however, this is for indoor uses and the proposed product also includes outdoor uses. Please note that the RED does include some outdoor residential uses. Based on this, we believe that the RED adequately covers this use pattern. Thus, according to the RED, the generic product chemistry, ecological effects, toxicology, and environmental fate data requirements have either been satisfied and/or waiver.

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Signature /		Name and Title: Catherine Rice,	Date
	athern	Agent for Espree Animal products, Inc.	1-4-07



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	DATA M	ATRIX FOR ACTIV			
Date January 4, 2007			EPA Reg. No./File Symbo	l ៉្តី66963 ៉ ូ	Page 1 of 2
Applicant's/Registrant's Name			Product	- 5000 	
Espree Animal Products, In	c. PO Box 3650, Grapevine, TX 76051		Aloe Herbal Horse Spra	av	
Ingredient(s): Cedarwood oil	(PC code 40505)		······································		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-	Product Identity, Composition, and				
62-	Analysis			ì	
				į.	
				·	
			ļ.		
63-	Physical/Chemical Properties				
TOXICOL	OGY				
81-1	Acute Oral Toxicity				
81-2	Acute Dermal Toxicity				
81-3	Acute Inhalation Toxicity				
81-4	Primary Eye Irritation				
81-5	Primary Dermal Irritation				
81-6	Skin Sensitization				
84-2A	Gene Mutation (Ames Test)				
84-2B	Structural Chromosomal Aberration				
84-4	Other Genotoxic Effects				
	CAL EFFECTS				
71-1A	Acute Avian Oral – Quail/Duck				
71-2B	Avian Dietary – Quail				
72-1A	Fish toxicity - Bluegill				
72-1 C	Fish Toxicity - Rainbow Trout				
72-2A	Invertebrate Toxicity			<u> </u>	
	MENTAL FATE				
(A) 835.2120/161-1	Hydrolysis				
O					

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DATA MATRIX FOR ACTIVE INGREDIENT						
Date January 4, 2007	EPA Reg. No./File Syn	nbol 5 66963 411 51115	Page 2 of 2			
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevi	Product Aloe Herbal Horse Spray					
Ingredient(s): Cedarwood oil (PC code 40505)						
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note		

FOOTNOTES

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Signature

Name and Title: Catherine Rice,
Agent for Espree Animals Products, Inc.

Date

1-4-07

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Signature

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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	DATA M	ATRIX FOR ACTIVE	INGREDIENT		
ate January 4, 2007			EPA Reg. No./File Symbol 36963-		
pplicant's/Registrant's Name			Product ""	yll	
spree Animai Products, in	c. PO Box 3650, Grapevine, TX 76051		Aloe Herbal Horse Spray		
ngredient(s): Cedarwood oil	(PC code 40505)				
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-	Product Identity, Composition, and				(1)
62-	Analysis	42319001	Whitney Corr-Pak (65813)	PAY	(3)
		42101201	Arbor American (65555)	OLD	
		41549503	Boswell R&D (63380)	OLD	
		42362601	P&M Consumer (66099)	PAY	(4)
		42362602	P&M Consumer (66099)	PAY	(4)
		42319002	Whitney Corr-Pak (65813)	PAY	(3)
63-	Physical/Chemical Properties	SATISIFIED			(1)
TOXICOL	OGY	7			
81-1	Acute Oral Toxicity	-		-	Waiver Reques
81-2	Acute Dermal Toxicity	-			Waiver Reques
81-3	Acute Inhalation Toxicity	-		#	Waiver Reques
81-4	Primary Eye Irritation	-		_	Waiver Reques
81-5	Primary Dermal Irritation			_	Waiver Reques
<u>81-6</u>	Skin Sensitization	-		-	Waiver Reques
84-2A	Gene Mutation (Ames Test)	-			Waiver Reques
84-2B	Structural Chromosomal Aberration			-	Waiver Reques
84-4	Other Genotoxic Effects	*		-	Waiver Reques
	ICAL EFFECTS				
71-1A	Acute Avian Ora(- Quail/Duck	-		<u>-</u>	Waiver Reques
71-2B	Avian Dietary – Quail	-		-	Waiver Reques
72-1A	Fish toxicity - Bluegill	-			Waiver Reques
72-1C	Fish Toxicity - Rainbow Trout			*	Waiver Reques
72-2A	Invertebrate Toxicity	-		*	Waiver Reques
	IMENTAL FATE				
835.2120/161-1	Hydrolysis	-		*	Waiver Reques

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Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc.

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DATA MATRIX	FOR ACTIVE INGREDIENT				
Date January 4, 2007	EPA Reg. No./File Symbol = 66933	EPA Reg. No./File Symbol > 66933-			
Applicant's/Registrant's Name & Address: Espree Animat Products, Inc. PO Box 3650, Grapevine, TX 76051	Product \$\tilde{	Product \$			
tngredient(s): Cedarwood oil (PC code 40505)					
Guideline Reference Number Guideline Study Name MRI	D Number Submitter	Status	Note		

FOOTNOTES

- 1. Per page 20 of the Cedarwood Oil RED, the product chemistry generic data requirements have been satisfied.
- 2. Per pages 21-22 of the Cedarwood Oil RED, the ecological effects, toxicology, and environmental fate generic data can be waived.
- 3. The Data Submitters List (9/30/2006) does not list this company (65813) as a data submitter for cedarwood oil. As a result, no offer to pay letter has been sent.
- The Data Submitters List (9/30/2006) does not list this company (66099) as a data submitter for cedarwood oil. As a result, no offer to pay letter
 has been sent.

Cedarwood oil (CAS Reg. No. 800-27-9, OPP chemical code 40505) is covered by the September 1993 Cedarwood Oil RED.

Pages 2-3 of the RED address the use profile:

Type of Pesticides: repellent/feeding depressant; fungicide

Use sites; indoor residential; domestic dwellings and their contents, pets/animals (presumable cats and dogs) and their living and steeping quarters

Target pets: fleas, moths, mildew Formulation types registered:

Ready to use spray - sprayed on animal bedding (0.48%)

Impregnated pet collar tag (0.5%)

Wood blocks (2-8%)

The proposed product will be used a fly repellent to be used on horses. The percent of Cedarwood oil will be 0.50%.

Rationale for Waiver Request: The use patterns addressed in the RED are slightly different from the proposed product's use pattern. However, both will be used on non-humans (pets vs. horses) to repet nuisance insects (fleas and moths vs. flies). Additionally, the towest rate covered by the RED is ready to use sprays at 0.48%. In the concentrated form, Aloe Herbal Horse Spray contains 0.50% cedarwood oil. According to the product's use directions, this concentrate is then to be diluted with a minimum of 4 parts water. Thus, the end use will contain 0.129% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic product chemistry data requirements have been satisfied and the ecological effects, toxicology, and environmental fate data requirements can be waived.

Signature O do d	Name and Title: Catherine Rice,	Date 1400
1 back of	Agent for Espree Animals Products, Inc.	1-7-01
EDA E 4 0578 56 40 671 544 1 Da		



Form Approved OMB No. 2070-0060

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	DATA M	IATRIX FOR ACTIV	ب تو بر ب		
Date January 4, 2007			EPA Reg. No./File Symbol 66963-	10 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Page 1 of 2
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray		
Ingredient(s): Eucalyptus Oil	(PC code 40503)				e Land
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61- 62-	Product Identity, Composition, and Analysis				
63-	Physical/Chemical Properties				
TOXICOL				····	
81-1	Acute Oral Toxicity				
81-2	Acute Dermal Toxicity				
81-3	Acute Inhalation Toxicity				
81-4	Primary Eye Irritation				
81-5	Primary Dermal Irritation				
81-6	Skin Sensitization			·	
84-2A	Gene Mutation (Ames Test)			<u> </u>	
84-2B	Structural Chromosomal Aberration				
84-4	Other Genotoxic Effects				
152-11	Repeat dose (14-day)				
152-23	Teratogenicity				
	CAL EFFECTS				
71-1A	Acute Avian Oral – Quail/Duck				
71-2A	Avian Dietary – Quail				
72-1A	Fish toxicity - Bluegill				
72-1C	Fish Toxicity - Rainbow Trout				
72-2A	Invertebrate Toxicity				
ENVIRON	MENTAL FATE				
161-1	Hydrolysis				

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Signature Lathura.

Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc.

Date /-4-07



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		DATA MATRIX FOR ACTIV	E INGREDIENT		
Date January 4, 2007			EPA Reg. No./File Symbol	3 56963 -3***	Page 2 of 2
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051			Product Aloe Herbal Horse Spray		
Ingredient(s): Eucalyptus Oil	(PC code 40503)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

FOOTNOTES

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Signature

Name and Title: Catherine Rice,
Agent for Espree Animals Products, Inc.

Date

1-4-07



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DATA MA	ATRIX FOR ACTIV	E INGREDIENT			
		EPA Reg. No./File Symbol 66963	2 2 2	Page 1 of 2	
		Product \$ 5			
Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		Aloe Herbal Horse Spray			
PC code 40503)					
Guideline Study Name	MRID Number	Submitter	Status	Note	
Product Identity, Composition, and					
Analysis					
Physical/Chemical Properties					
OGY					
Acute Oral Toxicity	-		-	Waiver Request (1)	
Acute Dermal Toxicity	-		+	Waiver Request (1)	
Acute Inhalation Toxicity	-		-	Waiver Request (1)	
Primary Eye Irritation	-		+	Waiver Request (1)	
Primary Dermal Irritation_	_		-	Waiver Request (1)	
Skin Sensitization	_		-	Waiver Request (1)	
Gene Mutation (Ames Test)	_		-	Waiver Request (1)	
Structural Chromosomal Aberration	-			Waiver Request (1)	
Other Genotoxic Effects	_		+	Waiver Request (1)	
Repeat dose (14-day)	-		-	Waiver Request (2)	
Teratogenicity	-		<u>-</u>	Waiver Request	
CAL EFFECTS					
Acute Avian Oral – Quail/Duck	**		-	Waiver Request (1)	
Avian Dietary – Quail	-		.	Waiver Request (1)	
Fish toxicity - Bluegill				Waiver Request (t)	
Fish Toxicity - Rainbow Trout	-		-	Waiver Request (1)	
Invertebrate Toxicity	-		-	Waiver Request (t)	
MENTAL FATE					
Hydrolysis	+			Waiver Request (1)	
	Address: C. PO Box 3650, Grapevine, TX 76051 (PC code 40503) Guideline Study Name Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral — Quail/Duck Avian Dietary — Quail Fish toxicity - Bluegill Fish Toxicity - Rainbow Trout Invertebrate Toxicity MENTAL FATE	Address: C. PO Box 3650, Grapevine, TX 76051 (PC code 40503) Guideline Study Name MRID Number Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity - Acute Dermal Toxicity - Acute Inhalation Toxicity - Primary Eye Irritation - Primary Dermal Irritation - Skin Sensitization - Gene Mutation (Ames Test) - Structural Chromosomal Aberration - Other Genotoxic Effects - Repeat dose (14-day) - Teratogenicity - CAL EFFECTS Acute Avian Oral – Quail/Duck - Avian Dietary – Quail - Fish toxicity - Bluegill - Fish Toxicity - Rainbow Trout - Invertebrate Toxicity - MENTAL FATE	EPA Reg. No./File Symbol 66363 Address: Product Aloe Herbal Horse Spray PC code 40503) Guideline Study Name Product Identity, Composition, and Analysis Physical/Chemical Properties OGY Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Skin Sensitization Gene Mutation (Ames Test) Structural Chromosomal Aberration Other Genotoxic Effects Repeat dose (14-day) Teratogenicity CAL EFFECTS Acute Avian Oral – Quail/Duck Avian Dietary – Quail Fish Toxicity – Brind August – Fish Toxicity – Invertebrate Toxicity Fish Toxicity – Buegill Fish Toxicity – Buegill Fish Toxicity – Rainbow Trout Invertebrate Toxicity MENTAL FATE	EPA Reg. No./File Symbol 66383 Product Aloe Herbal Horse Spray	

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Signature CHALLA - 1

Name and Title: Catherine Rice, Agent for Espree Animals Products, Inc. Date 1-4-0



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	D	ATA MATRIX FOR ACTIV		e we want to the contract of t		
Date January 4, 2007			EPA Reg. No./File Symbol	Page 2 of 2		
Applicant's/Registrant's Name & Address: Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 76051		951	Product Aloe Herbal Horse Spray			
Ingredient(s): Eucalyptus Oil	(PC code 40503)					
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note	

FOOTNOTES

- 1. Per pages 63 and 64 of the Flower and Vegetables Oils RED, the ecological effects, toxicology, and environmental fate generic data can be waived.
- Waiver requested since the proposed end-use product will be for non-human use.

Eucalyptus oil (CAS Reg. No. 8000-48-4, OPP chemical code 40503) is covered by the December 1993 Flower and Vegetable Oils RED. Page 7 of the RED addresses the use profile:

Type of Pesticide: repellent and insect feeding depressant

Use Sites: pets Target pests: fleas

Formulation types registered: impregnated material (collar)

Method and Rates of application Equipment - by hand

Method and Rate - up to one ounce per animal

Timing - as needed

Use Practice Limitation: none

Product covered by RED is end-use product at 1.00%.

The proposed product will be used a fly repellent to be used on horses. The percent of Eucalyptus oil will be 0.378%.

Rationale for Waiver Request: The use pattern addressed in the RED is slightly different from the proposed product's use pattern. However, both will be used on nonhumans (pets vs. horses) to repel nuisance insects (fleas vs. flies). Further the RED covers end-use products rates at 1.00%. In the concentrated form, Aloe Herbal Horse Spray contains 0.378% eucalyptus oil. According to the product's use directions, this product is then to be diluted with a minimum of 4 parts water. Thus, the end use will contain 0.095% maximum. Based on this, we believe that the RED adequately protects this use pattern. Thus, according to the RED, the generic ecological effects, toxicology, and environmental fate data requirements can be waived.

Signature / /		Name and Title: Catherine Rice,	Date
1 (.6	Lthur A	Agent for Espree Animals Products, Inc.	1-4-07



Pesticide Data Submitters List

By Active Chemical Code – September 30, 2006 Edition

REPORT OF PESTICIDE DATA SUBMITTERS IN EPA FILES BY CHEMICAL

CHEMICAL CHEMICAL NAME 000011 Methane, iodo-

> COMPANY# 066330 ARYSTA LIFESCIENCE NORTH AMERICA CORPORATION * DATA TYPES * PARK WEST II 15401 WESTON PKWY SUITE 150 EU AT EC FW EF OF CARY, NC 27513

XX XΧ

CHEMICAL CHEMICAL NAME 000013 Trichlorofluoromethane

> COMPANY# 000499 WHITMIRE MICRO-GEN RESEARCH LABORATORIES INC * DATA TYPES * 3568 TREE CT INDUSTRIAL BLVD EU AT EC FW EF OT ST LOUIS, MO 63122 XX XX

COMPANY# 066607 SPRAY DRIFT TASK FORCE * DATA TYPES * 1900 K STREET, NW EU AT EC FM EF OT WASHINGTON, DC 20006

CHEMICAL CHEMICAL NAME

000014 Dichlorodifluoromethane

> COMPANY# 000499 WHITMIRE MICRO-GEN RESEARCH LABORATORIES INC * DATA TYPES * 3568 TREE CT INDUSTRIAL BLVD EU AT EC FW EF OT ST LOUIS, MO 63122

XX

XX XX

COMPANY# 066607 SPRAY DRIFT TASK FORCE * DATA TYPES * 1900 K STREET, NM EU AT EC FW EF OT WASHINGTON, DC 20006

CHEMICAL CHEMICAL NAME 000101 Glycolic acid

> COMPANY# 005813 CLOROX CO., THE * DATA TYPES * C/O PS&RC EU AT EC FW EF OT PO BOX 493

PLEASANTON, CA 94566 XX

COMPANY# 071654 E.I. DUPONT DE NEMOURS AND COMPANY * DATA TYPES * DUPONT CHEMICAL SOLUTIONS ENTERPRISE EU AT EC FW EF OT 90 BOX 80402 XX XX XX XX WILMINGTON, DE 19880

CHEMICAL CHEMICAL NAME 000111 Aluminum powder

> COMPANY# 001913 DRACKETT PRODUCTS CO. THE * DATA TYPES * 8310 16TH ST. MS486 EU AT EC FW EF OT STURTEVANT, WI 53177

> > page 1 of 820

```
EU AT EC FW EF OT
                              EL CAJON, CA 92020
           COMPANY# 074286
                              DISHWASHER MAGIC
           * DATA TYPES *
                              PO BOX 640
           EU AT EC FW EF OT
                              HOCKESSIN, DE 197070640
           ·COMPANY#
                    074331
                              STERIFX INC.
           * DATA TYPES *
                              INTERTECH SCIENCE PARK
           EU AT EC FW EF OT
                              1431 DALZELL STREET
              XX
                               SHREVEPORT, LA 71103
           COMPANY# 074888
                              RESIDENTIAL EXPOSURE JOINT VENTURE (REJV)
           * DATA TYPES *
                              900 17TH STREET, NW, SUITE 300
           EU AT EC FW EF OT
                              WASHINGTON, DC 20006
           COMPANY#
                    081857
                              BIOLOGICAL SOLUTIONS LLC
           * DATA TYPES *
                              900 E LIBERTY ST.
           EU AT EC FW EF OT
                              SUMTER, SC 29153
                      XX
 CHEMICAL CHEMICAL NAME
  021802 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, ammonium salt
           COMPANY# 005197
                             SYSTEMS GENERAL, INC.
           * DATA TYPES *
EU AT EC FW EF OT
                              PO BOX 152170
                              IRVING, TX 75015
                      XX
CHEMICAL CHEMICAL NAME
  021901
          Oil of citronella
           COMPANY# 000059
                             COOPERS ANIMAL HEALTH INC
           * DATA TYPES *
                              421 EAST HAWLEY ST
           EU AT EC FW EF OT
                              MUNDELEIN, IL 60060
             XX
                      XX
           COMPANY# 000134
                              HESS & CLARK INC
           * DATA TYPES *
                              110 HOPKINS DRIVE
           EU AT EC FW EF OT
                              RANDOLPH, WI 53956
                XX XX
           COMPANY# 000270
                              FARNAM COMPANIES INC
           * DATA TYPES *
                              PO BOX 34820
           EU AT EC FW EF OT
                              PHOENIX, AZ 85067
                      XX
           COMPANY# 009201
                              CANDLE CORP OF AMERICA
           * DATA TYPES *
                              999 EAST TOUHY AVE. SUITE 450
           EU AT EC FW EF OT
                              DES PLAINS, IL 60018
             XX XX XX
           COMPANY# 065233
                              PRIMAVERA LABORATORIES, INC
           * DATA TYPES *
                              1000 POTOMAC STREET, NW, 5TH FLOOR
           EU AT EC FW EF OT
                              WASHINGTON, DC 20007
                         XX
           COMPANY# 066607
                              SPRAY DRIFT TASK FORCE
           * DATA TYPES *
                              1900 K STREET, NW
           EU AT EC FW EF OT
                              WASHINGTON, DC 20006
                         XX
           COMPANY# 073878
                              GLOBAL CONTAINER GROUP TRADING COMPANY, LLC
           * DATA TYPES *
                              1101 17TH ST NW, SUITE 500
           EU AT EC FW EF OT
                              WASHINGTON, DC 20036
                      XX XX
           COMPANY# 074888
                              RESIDENTIAL EXPOSURE JOINT VENTURE (REJV)
```

page 94 of 820

244

```
EU AT EC FW EF OT
                             WASHINGTON, DC 20006
         COMPANY# 080657
                             THE COMPANION GROUP
         * DATA TYPES *
                             30856 ROCKY ROAD
         EU AT EC FW EF OT
                             GREELEY, CO 806319375
         COMPANY#
                   082868
                             ROSEMONT VENTURES, INC.
         * DATA TYPES *
                             ONE GATEWAY CENTER, SUITE 409
         EU AT EC FW EF OT
                             NEWTON, MA 02458
                     ХX
CHEMICAL CHEMICAL NAME
 022003 Coal tar
         COMPANY#
                   066607
                             SPRAY DRIFT TASK FORCE
         * DATA TYPES *
                             1900 K STREET, NW
         EU AT EC FW EF OT
                             WASHINGTON, DC 20006
                        XX
CHEMICAL CHEMICAL NAME
022101
         Cresylic acid, coal tar acids, coal tar phenols, or coal tar cresols
         COMPANY# 000052
                             WEST CHEMICAL PRODUCTS, INC.
         * DATA TYPES *
                            WEST PENETONE CORPORATION
         EU AT EC FW EF OT
                             700 GOTHAM PARKWAY
                    XX
                            CARLSTADT, NJ 07072
         COMPANY# 000059
                            COOPERS ANIMAL HEALTH INC
         * DATA TYPES *
                             421 EAST HAWLEY ST
         EU AT EC FW EF OT
                            MUNDELEIN, IL 60060
                    XX
         COMPANY# 000134
                            HESS & CLARK INC
         * DATA TYPES *
                            110 HOPKINS DRIVE
         EU AT EC FW EF OT
                            RANDOLPH, WI 53956
                    XX
         COMPANY# 000363
                            COOPERS CREEK CHEMICAL CORP
         * DATA TYPES *
                            W/S RIVER ROAD
         EU AT EC FW EF OT
                            WEST CONSHOHOCKEN, PA 19428
                    XX
         COMPANY#
                  000475
                            RECKITT BENCKISER INC.
         * DATA TYPES *
                            MORRIS CORPORATE CENTER IV
         EU AT EC FW EF OT
                            PO BOX 0225
                    XX
                            PARSIPPANY, NJ 07054
         COMPANY#
                  000551
                           CAMERON BAIRD
         * DATA TYPES *
                            445 TILDEN ROAD
         EU AT EC FW EF OT
                            SCITUATE, MA 02066
                    XΧ
         COMPANY#
                  000984
                            WHITMOYER LAB INC
         * DATA TYPES *
                            19 NORTH RAILROAD ST.
                            MYERSTOWN, PA 17067
         EU AT EC FW EF OT
                    ХX
         COMPANY#
                  002155
                           I, SCHNEID
         * DATA TYPES *
                            PO BOX 16247
         EU AT EC FW EF OT
                            ATLANTA, GA 30321
                    ХX
                  006035
         COMPANY#
                            VINELAND LABORATORIES
         * DATA TYPES *
                            2285 E. LANDIS AVE.
         EU AT EC FW EF OT
                            VINELAND, NJ 08360
           ХX
```

900 17TH STREET, NW, SUITE 300

* DATA TYPES *

* DATA TYPES * 9055 FREEWAY DRIVE EU AT EC FW EF OT MACEDONIA, OH 44056 XX COMPANY# 000731 SUDBURY LABORATORY INC * DATA TYPES * 6 OCTOBER HILL RD. EU AT EC FW EF OT HOLLISTON, MA 01746 XX COMPANY# 004169 ABORN CHEMICAL INDUSTRIES INC * DATA TYPES * 92 YORK AVE EU AT EC FW EF OT RANDOLPH, MA 02368 XX COMPANY# 010141 HOLLISTON LABORATORIES INC * DATA TYPES * 440 TOTTEN POND RD EU AT EC FW EF OT WALTHAM, MA 02154 XX COMPANY# 066607 SPRAY DRIFT TASK FORCE * DATA TYPES * 1900 K STREET, NW EU AT EC FW EF OT WASHINGTON, DC 20006 XXCHEMICAL CHEMICAL NAME 040503 Oil of eucalyptus COMPANY# 000305 UNTIED INDUSTRIES CORP. * DATA TYPES * D/B/A NPC BRANDS, INC. EU AT EC FW EF OT PO BOX 4406 XX BRIDGETON, MO 63044 COMPANY# 010487 THE DONNELLY COMPANY * DATA TYPES * 6002 TOPEKA DRIVE EU AT EC FW EF OT TARZANA, CA 91356 XX COMPANY# 066607 SPRAY DRIFT TASK FORCE * DATA TYPES * 1900 K STREET, NW EU AT EC FW EF OT WASHINGTON, DC 20006 XX COMPANY# 074888 RESIDENTIAL EXPOSURE JOINT VENTURE (REJV) * DATA TYPES * 900 17TH STREET, NW, SUITE 300 EU AT EC FW EF OT WASHINGTON, DC 20006 XX CHEMICAL CHEMICAL NAME 040505 Cedarwood oil COMPANY# 010487 THE DONNELLY COMPANY * DATA TYPES * 6002 TOPEKA DRIVE EU AT EC FW EF OT TARZANA, CA 91356 XX CHEMICAL CHEMICAL NAME 040506 Cinnamaldehyde COMPANY# 041847 MOBIL CHEMICAL COMPANY * DATA TYPES * 729 PITTSFORD-PALMYRA RD, TECHNICAL CENTER RT #31 EU AT EC FW EF OT MACEDON, NY 14502 XX XX XX COMPANY# 051036 BASE SPARKS LLC * DATA TYPES * PO BOX 13528 EU AT EC FW EF OT RESEARCH TRIANGLE PARK, NC 27709 XX COMPANY# 058866 PROGUARD INC * DATA TYPES * PO BOX 550

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401 M Street, S.W.Washington, D.C. 20460

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SUMMAR	Y OF THE PHYSI	CAL/CHEMICAI	L PROPERTIES (PR N	otice 98-1)
1. PRODUCT NAME:	2. Reg. No.			
Aloe Herbal l		66963- (not yet assigned		
3. COMPANY NAME:	4. SUBMISSION DATE:			
Espree Animal I	rroducts, the.	// · · · · · · · · · · · · · · · · · · 		January 4, 2007
5. FIRST SUBMISSION X 6. RESUBMISSION	7. PESTICIDE TY	PE: Antimicrobia	l 	10. REGISTRATION X
8. FORMULATED MANUFACT	URING-USE PRODUC	T or 9. END-U	SE PRODUCT [X]	II. REREGISTRATION
I3. PRODUCT MANAGER OR C	HEMICAL REVIEW	MANAGER # / NAMI	E (IF KNOWN):	12. REREG CASE #
Marshall Swindell, AD T			- (~ /·	
14. GUIDELINE REFERENCE NO.(GRN)/TITLE		LITATIVE DESRIPTIO RE APPLICABLE AND		I6. MRID or REPORT NO.
Group	B, Series 830-Phys	sical and Chemica	l Properties (40CFR 15	8.190)
- 6302 Color	Clear, colorless			Not yet assigned
- 6303 Physical State	Liquid			Not yet assigned
-6304 Odor	Not Required - per	PR Notice 95-2		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
-6314 Oxidation/Reduction		0	bservation	Not yet assigned
Citemical Incompatibility	Exposure	Upon Mixing	After 24 hours	
	System	· · · · · · · · · · · · · · · · · · ·	exposure	
	Powdered Iron	No signs of reaction	No signs of reaction	
	Potassium	No signs of	No signs of reaction	
	permanganate	reaction		
	Water	No signs of	No signs of reaction	
		reaction		
	Monoammonium phospate	No signs of reaction	No signs of reaction	
- 6315 Flammability/Flame	**************************************	**************************************	Spray does not contain any	**************************************
Extension	combustible liquids	#XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
-6316 Explodability	Not Applicable sind explosive ingredica		Spray does not contain any	
- 6317 Storage Stability	Waiver requested t 3.			
-6319 Miscibility	Not Applicable since Aloc Herbal horse Spray is not to be diluted with petroleum solvents.			
- 6320 Corrosion Characteristics	This study is curre completion.			
- 6321 Dielectric Breakdown Voltage	Not Applicable since Aloe Herbal Horse Spriy is not for use around			
~ 7000 pH	4.90 (25C)		<u> </u>	Not yet assigned
-7111 Vicosity	18.266 mm ² /s (cSt)	(22C)		Not yet assigned
- 7300 Density/Relative Density/	0.8435	 	= := /= /=	5
Bulk Density	1 1 1	<u> </u>		Not yet assigned

EPA Form 8570-36 (07/JAN/1998)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. Washington, D.C. 20460

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SUMMAI	RY OF THE PHYSI	CAL/CHEMICAL	L PROPERTIES (PR N	otice 98-1)	
1. PRODUCT NAME:	1. PRODUCT NAME:				
Aloe Herbal	66963- (not yet assigned)				
3. COMPANY NAME:	4. SUBMISSION DATE:				
Espree Animal	Products, Inc.			January 4, 2007	
5. FIRST SUBMISSION [X] 6. RESUBMISSION []	7. PESTICIDE TY	PE: Antimicrobia	l	10. REGISTRATION X	
8. FORMULATED MANUFAC	TURING-USE PRODUC	CT] or 9. END-U	SE PRODUCT X	II. REREGISTRATION [[
t3. PRODUCT MANAGER OR Marshall Swindell, AD		MANAGER#/NAMI	E (IF KNOWN):	12. REREG CASE#	
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUA WHEI	LITATIVE DESRIPTION RE APPLICABLE AND D	N/METHOD(s) IJSED REFERENCES	16. MRID or REPORT NO.	
Grou	p B, Series 830-Phys	sical and Chemica	l Properties (40CFR 15	8.190)	
- 6302 Color	Clear, coloriess			Not yet assigned	
- 6303 Physical State	Liquid			Not yet assigned	
-6304 Odor	Not Required – per				
-6314 Oxidation/Reduction Chemical incompatibility	Exposure System	Upon Mixing	After 24 hours exposure	Not yet assigned	
	Powdered Iron	No signs of reaction	No signs of reaction		
	Potassium permanganate	No signs of reaction	No signs of reaction		
	Water	No signs of reaction	No signs of reaction		
	Monoammonium phospate	No signs of reaction	No signs of reaction		
- 6315 Flammability/Flamc Extension	Not Applicable sine		Spray does not contain any		
-63t6 Explodability		e Aloc Herbal Horse S	Spray does not contain any	The state of the s	
-6317 Storage Stability	~ ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Waiver requested under 40 CFR 158.155(f). Please refer to Volume			
- 6319 Miscibility	25 -7-24-11-11-1	Not Applicable since Aloe Herbal horse Spray is not to be diluted			
- 6320 Corrosion Characteristics		This study is currently being conducted. Will be submitted on			
- 6321 Dielectric Breakdown Voltage		Not Applicable since Aloe Herbal Horse Spriy is not for use around			
- 7000 pH	4.90 (25C)	**************************************	**************************************	Not yet assigned	
-7111 Vicosity	t8.266 mm ² /s (cSt)	(22C)		Not yet assigned	
- 7300 Density/Relative Density/ Bulk Density	0.8435			Not yet assigned	

EPA Form 8570-36 (07/JAN/1998)



401 M Street, S.W. WASHINGTON, D.C. 20460

ION AGENCY

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	······			
Certification with Res	pect to Citation of	Data		
Applicant's/Registrant's Name, Address and Telephone Number Espree Animal Products, Inc. PO Box 3650, Grapevine, TX 7605	1	EPA Registration Number/ File Symbol 66963- (not yet assigned)		
Active Ingredient(s) and/or representative test compound(s): Citronella Oil (PC code 021901), Cedarwood Oil (PC code 40505), (PC code 40503)	Citronella Oil (PC code 021901), Cedarwood Oil (PC code 40505), Eucalyptus Oil			
General use pattern(s) (list all those claimed for this product using 40 C Indoor non-food	FR Part 158)	Product Name Aloe Herbal Horse Spray		
NOTE: If your product is a 100% repackaging of another purchased El do not need to submit this form. You must submit the Formulator's Exe				
I am responding to a Data Call-In Notice, and have included with Matrix form should be used for this purpose).	this form a list of con	npanies sent offers of compensation (the Data		
SECTION I: METHOD OF DATAS	SUPPORT (Check o	ne method only)		
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the select	selective method of support (or cite-all option ctive method), and have included with this form a of data requirements (the Data Matrix form must		
SECTION II: GENER	RAL OFFER TO PA	Υ		
[Required if using the cite-all method or when using the cite-all option u	nder the selective me	thod to satisfy one or more data requirements]		
I hereby offer and agree to pay compensation, to other persons, wi FIFRA.	th regard to the appro	oval of this application, to the extent required by		
SECTION III: C	ERTIFICATION			
I certify that this apolication for registration, this form for rerect or cited in the application for registration, the form for reregistration, o selective method is indicated in Section I, this application is supported effects of this product or an identical or substantially similar product, or data that would be required to be submitted under the data requireme application sought the initial registration of a product of identical or sin	r this Data Call-In red t by all data in the Ag or one or more of the onts in effect on the d	sponse. In addition, if cite-all option under the gency's files that (1) concern the properties or ingredients in this product; and (2) is a type of ate of approval of this application if the		
l certify that for each exclusive use study cited in support of t I have obtained the written permission of the original submitter to cite	his registration or rer that study.	egistration, that I am the original submitter or that		
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.				
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.				
I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.				
Signature, D. Date 1-4.0	1 **	nted Name and Title Rice, Agent for Espree Animal Products, Inc.		
EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only	Paner version	<u> </u>		

Fly Repellent

1:5 Concentrate Repels Flies, Gnats and Mosquitoes Contains Aloe Vera, Sunscreen and Coat Conditioners 32 Fl oz. (946 ml)

Active Ingredients:

 Citronella Oil
 0.75%

 Cedarwood Oil
 0.50%

 Eucalyptus Oil
 0.378%

 Other Ingredients:
 98.372%

 TOTAL:
 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

EPA Reg. No. 66963-I

EPA Est. No.: 66963-TX-001

A gentle, effective blend of natural botanical oils to repel flies, gnats, mosquitoes and other flying insects on horses. Contains coat conditioners and sunscreen which promote a healthy coat and protection from the sun. Made with human grade ingredients, Aloe Herbal Horse Spray provides your horse long lasting protection.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. SHAKE CONTIANER BEFORE EACH APPLICATION.

General Directions: Apply in a covered area (i.e., stalls, barn, etc.). Brush coat to remove excess dirt and dust. For best results apply to a clean horse.

<u>Dilution Directions</u>: To be used in a clean spray container of your choice. Dilute with 5 parts water to 1 part horse spray. For more stubborn cases, dilute 4 parts water to 1 part horse spray.

Application Directions: Hold spray container 10 to 12 inches from coat for best application. Apply with cloth to facial area. Do not use on animals intended for human consumption.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store only in a cool, dry area inaccessible to children and pets. Keep container tightly closed when not in use.

PESTICIDE DESPOSAL: Wastes resulting from use of this product may be used on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

FIRST AID				
Have the product container or label with you when calling a poison control center or doctor, or				
going for treatment.				
If on skin: • Take off contaminated clothing.				
	• Rinse skin immediately with plenty of water for 15-20 minutes.			
	Call a poison control center or doctor for treatment advice.			
If in eyes:	in eyes: • Hold eye open and rinse slowly and gently with water for I5-20 minutes.			
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.			
	Call a poison control center or doctor for further treatment advice.			

Manufactured By:
Espree Animal Products, Inc.
3250 Stone Myers Parkway
Grapevine, TX 76051
www.espree.com

1-800-328-1317

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FOR (OFFICIAL -	USE	
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FILE SYMBOL

66963 -I

REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE	SUBMITTED BY (/)				
SUBMITTED	APPLICANT	BASIC SUPPLIER			
JAN 1 1 2007					
	77				
·	5				

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharamacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal insecticide, Fungicide, and Rodenticide Act."

·					
Page is not included in this copy.					
Pages 260 through 265 are not included in this copy.					
The material not included contains the following type of information:					
Identity of product inert ingredients.					
Identity of product impurities.					
Description of the product manufacturing process.					
Description of quality control procedures.					
Identity of the source of product ingredients.					
Sales or other commercial/financial information.					
A draft product label.					
X The product confidential statement of formula.					
Information about a pending registration action.					
FIFRA registration data.					
The document is a duplicate of page(s)					
The document is not responsive to the request.					
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.					
Attorney-Client Privilege.					
Claimed Confidential by submitter upon submission to the Agency.					
Internal Deliberative Information.					

 $^{^{\}star}$ The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.